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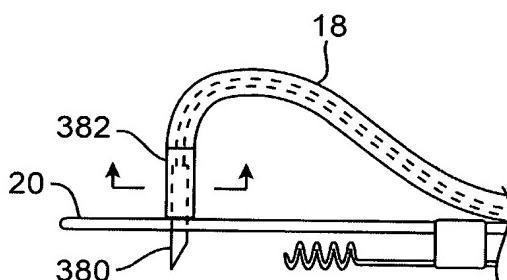
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(54) Title: NEEDLE ASSEMBLY FOR TISSUE MANIPULATION



end. The anchor assembly is positioned distally of the pusher within the sheath.

(57) Abstract: Needle assemblies for tissue manipulation are described herein. In creating tissue folds within the body of a patient, a tissue manipulation assembly may generally have an elongate tubular member, an engagement member slidably disposed through the tubular member and a distal end adapted to engage tissue via a helical member, tissue stabilizing members positioned at the tubular member distal end which are adapted to stabilize tissue therebetween, and a delivery tube pivotable about the tissue stabilizer. A needle deployment assembly is deployable through the tissue manipulation assembly via a handle assembly, through the tubular member, and into or through tissue. An elongate pusher is translationally disposed within a sheath of the needle deployment assembly and can be urged distally for deploying an anchor assembly from the sheath distal

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NEEDLE ASSEMBLY FOR TISSUE MANIPULATION

BACKGROUND OF THE INVENTION

[0001] Field of the Invention. The present invention relates to methods and apparatus for forming and securing gastrointestinal (“GI”) tissue folds. More particularly, the present invention relates to methods and apparatus for reducing the effective cross-sectional area of a gastrointestinal lumen.

[0002] Morbid obesity is a serious medical condition pervasive in the United States and other countries. Its complications include hypertension, diabetes, coronary artery disease, stroke, congestive heart failure, multiple orthopedic problems and pulmonary insufficiency with markedly decreased life expectancy.

[0003] A number of surgical techniques have been developed to treat morbid obesity, e.g., bypassing an absorptive surface of the small intestine, or reducing the stomach size. However, many conventional surgical procedures may present numerous life-threatening post-operative complications, and may cause atypical diarrhea, electrolytic imbalance, unpredictable weight loss and reflux of nutritious chyme proximal to the site of the anastomosis.

[0004] Furthermore, the sutures or staples that are often used in these surgical procedures typically require extensive training by the clinician to achieve competent use, and may concentrate significant force over a small surface area of the tissue, thereby potentially causing the suture or staple to tear through the tissue. Many of the surgical procedures require regions of tissue within the body to be approximated towards one another and reliably secured. The gastrointestinal lumen includes four tissue layers, wherein the mucosa layer is the inner-most tissue layer followed by connective tissue, the muscularis layer and the serosa layer.

[0005] One problem with conventional gastrointestinal reduction systems is that the anchors (or staples) should engage at least the muscularis tissue layer in order to provide a proper foundation. In other words, the mucosa and connective tissue layers typically are not strong enough to sustain the tensile loads imposed by normal movement of the stomach wall during ingestion and processing of food. In particular, these layers tend to stretch elastically rather than firmly hold the anchors (or staples) in position, and accordingly, the more rigid

muscularis and/or serosa layer should ideally be engaged. This problem of capturing the muscularis or serosa layers becomes particularly acute where it is desired to place an anchor or other apparatus transesophageally rather than intra-operatively, since care must be taken in piercing the tough stomach wall not to inadvertently puncture adjacent tissue or organs.

5 [0006] One conventional method for securing anchors within a body lumen to the tissue is to utilize sewing devices to suture the stomach wall into folds. This procedure typically involves advancing a sewing instrument through the working channel of an endoscope and into the stomach and against the stomach wall tissue. The contacted tissue is then typically drawn into the sewing instrument where one or more sutures or tags are implanted to hold the
10 suctioned tissue in a folded condition known as a plication. Another method involves manually creating sutures for securing the plication.

[0007] One of the problems associated with these types of procedures is the time and number of intubations needed to perform the various procedures endoscopically. Another problem is the time required to complete a plication from the surrounding tissue with the
15 body lumen. In the period of time that a patient is anesthetized, procedures such as for the treatment of morbid obesity or for GERD must be performed to completion. Accordingly, the placement and securement of the tissue plication should ideally be relatively quick and performed with a minimal level of confidence.

[0008] Another problem with conventional methods involves ensuring that the staple, knotted suture, or clip is secured tightly against the tissue and that the newly created plication will not relax under any slack which may be created by slipping staples, knots, or clips. Other conventional tissue securement devices such as suture anchors, twist ties, crimps, etc. are also often used to prevent sutures from slipping through tissue. However, many of these types of devices are typically large and unsuitable for low-profile delivery through the body,
25 e.g., transesophageally.

[0009] Moreover, when grasping or clamping onto or upon the layers of tissue with conventional anchors, sutures, staples, clips, etc., many of these devices are configured to be placed only after the tissue has been plicated and not during the actual plication procedure.

BRIEF SUMMARY OF THE INVENTION

30 [0010] In creating tissue plications, a tissue plication tool having a distal tip may be advanced (transorally, transgastrically, etc.) into the stomach. The tissue may be engaged or

grasped and the engaged tissue may be moved to a proximal position relative to the tip of the device, thereby providing a substantially uniform plication of predetermined size. In order to first create the plication within a body lumen of a patient, various methods and devices may be implemented. The anchoring and securement devices may be delivered and positioned via
5 an endoscopic apparatus that engages a tissue wall of the gastrointestinal lumen, creates one or more tissue folds, and disposes one or more of the anchors through the tissue fold(s). The tissue anchor(s) may be disposed through the muscularis and/or serosa layers of the gastrointestinal lumen.

[0011] One variation of an apparatus which may be used to manipulate tissue and create a
10 tissue fold may generally comprise an elongate tubular member having a proximal end, a distal end, and a length therebetween, an engagement member which is slidably disposed through the tubular member and having a distal end adapted to engage tissue, a first stabilizing member and a second stabilizing member positioned at the tubular member distal end and adapted to stabilize tissue therebetween, wherein the first and second stabilizing
15 members are further adapted to be angled relative to a longitudinal axis of the elongate tubular member, and a delivery tube adapted to pivot about the first stabilizing member

[0012] The elongate tubular member or launch tube may be advanced from its proximal end at a handle located outside a patient's body such that a portion of the launch tube is forced to rotate at a hinge or pivot and reconfigure itself such that the distal portion forms a
20 curved or arcuate shape that positions the launch tube opening perpendicularly relative to a longitudinal axis of body. The launch tube, or at least a portion of the launch tube, is preferably fabricated from a highly flexible material or it may be fabricated, e.g., from Nitinol tubing material which is adapted to flex, e.g., via circumferential slots, to permit bending.

25 [0013] The tissue engagement member may be an elongate member, e.g., a wire, hypotube, etc., which has a tissue grasper or engager attached or integrally formed at its distal end for grasping or engaging the tissue. In one variation, the tissue grasper may be formed as a helix having a uniform outer diameter with a constant pitch. The helix 80 may be attached to an elongate acquisition member via any suitable fastening method, e.g., adhesives, solder, etc.
30 Alternatively, the helix may be integrally formed from the distal portion of the acquisition member by winding or coiling the distal portion in a helix configuration.

[0014] Alternative configurations for the helix may include a number of variations. For instance, the helix may have a varied pitch or one or more regions with varying pitch along the length of the helix. Alternatively, a helix may include a piercing needle extending through the center and protruding distally of the helix. Other variations may include a dual-helix, a helix having a decreasing diameter, the addition of an articulatable grasping jaw in combination with the helix. Moreover, the helix may be completely or partially hollow with one or more deployable anchors positioned within or advanced through hollow helix.

[0015] Alternative variations for the helix may also include optional measures to prevent the helix from inadvertently damaging any surrounding tissue. For example, one variation may include a sheathed helix assembly while another variation may have an insertion member which defines an atraumatic distal end which may be advanced through the center of the helix. Another alternative may include a helix which may be configured to reconfigure itself into a straightened configuration to facilitate its removal from the tissue. In such a device, the helix may be electrically connected via a connection of wires to a power source.

[0016] In addition to the variations of the tissue grasper or helix, the stabilizing members, otherwise called extension members, may also include various embodiments. For instance, the upper and/or lower extension members or bails may also be configured with any of the helix variations as practicable. Although the upper and lower extension members or bails may be maintained rigidly relative to one another, the upper and/or lower extension members may be alternatively configured to articulate from a closed to an open configuration or conversely from an open to a closed configuration for facilitating manipulation or stabilization of tissue drawn between the bail members.

[0017] Articulation or manipulation of the extension members may be accomplished via any number of methods. For instance, the upper and/or lower extension members may include a pivoting cam member, a linkage assembly, biased extension members which are urged closed or open, etc. Moreover, lower extension member may alternatively be extended in length relative to upper extension member or one or both extension members may be configured to have atraumatic blunted ends to prevent inadvertently damaging surrounding tissue.

[0018] Moreover, it is preferable to have sufficient clearance with respect to the lower extension member so that unhindered deployment of the needle assembly or anchors from the apparatus is facilitated. One method for ensuring unhindered deployment is via a lower

extension member having a split opening defined near or at its distal end. Alternatively, the lower extension member may be configured to create a “C”-shaped member which allows for an opening along the member.

[0019] Alternatively, the lower extension member may be fabricated from a non-

5 conductive material upon which wires may be integrated such that the entire lower member may be electrically conductive to selectively ablate regions of tissue, if so desired.

[0020] Aside from creating ablation regions, the tissue manipulation assembly may be connected to the tubular body via a hinged or segmented articulatable portion which allows the tissue manipulation assembly to be reconfigured from a low-profile configuration

10 straightened relative to the tubular body to an articulated configuration where the assembly forms an angle relative to the tubular body. The articulatable portion may be configured to allow the assembly to become articulated in a single plane or it may also be configured to allow a full range of motion unconstrained to a single plane relative to tubular body to facilitate manipulation of the tissue.

15 [0021] In addition to the extension members, the launch tube itself may be fabricated from a metal such as Nitinol, stainless steel, titanium, etc., to facilitate the flexure of the tube. Such a tube may be selectively scored or cut to enhance the directional flexibility of the tube.

[0022] The launch tube may be advanced distally until the deployed needle body of the needle assembly emerges from the launch tube perpendicularly to the tissue drawn between 20 the extension members, and particularly to upper extension member. Thus, the distal opening of the launch tube may be configured to form an angle, β , relative generally to the tissue manipulation assembly. The angle, β , is preferably close to 90° but it may range widely depending upon the amount of tissue grasped as well as the angle desired.

[0023] A distal portion of the launch tube may also be modified to include an extended 25 portion which is configured to remain straight even when the launch tube is flexed into its deployment configuration. This extended portion may provide additional columnar support to a needle body passing through during needle deployment from the launch tube to help ensure the linear deployment of the needle body into or through the tissue.

[0024] Alternatively, the needle body may define a cross-sectional shape, other than

30 circular, which is keyed to the extended distal portion of the launch tube. The needle body may be keyed to the launch tube to ensure a specified deployment trajectory of the needle

body from the keyed launch tube. Alternatively, the launch tube may be overdriven relative to the tissue manipulation assembly and upper extension member.

[0025] The needle assembly which is advanced through the launch tube may generally comprise the needle body attached or integrally formed with a tubular catheter or push tube.

5 The needle body is preferably a hollow tapered needle which is configured to pierce into and through tissue. The needle body may have a variety of tapered piercing ends to facilitate its entry into tissue. One variation which may be utilized to ensure the needle trajectory through the tissue may include a curvable needle body deployed from the launch tube. Such a needle body may be constrained into a straightened configuration when positioned within the launch
10 tube. However, once deployed the needle body may be adapted to reconfigure itself into a curved configuration directed towards the tissue manipulation assembly. The needle body may be curved via an anvil configured to receive and deflect the travel of the needle body into a curved needle body.

[0026] Alternatively, the needle body may be replaced with a fiber optic needle which may

15 be deployed through the launch tube to provide visualization of the tissue region prior to, during, or after anchor deployment. In another alternative, advancement of the needle body into and/or through the tissue may be facilitated via an ultrasonic vibrating needle body or a torqueable needle body which may be torqued about its proximal end to facilitate entry into the tissue. The torqueable needle body may be connected via a catheter length having high-
20 torque characteristics.

[0027] Rather than deploying anchors from the needle assembly via a distal opening in the needle body, the tissue anchor may alternatively be deployed through one or more side openings defined proximally of the distal tip of the needle body. In yet another alternative, the needle body may have gradations or indicators along its surface to provide a visual

25 indication to the surgeon or physician of the position of the needle body when advanced into or through the tissue or when deployed from the launch tube.

[0028] Moreover, the outer surface of the needle body may be dimpled to enhance the visualization of the needle body within the patient body. Moreover, dimples may also enhance the visualization of needle body under ultrasound imaging. Aside from dimples, the
30 outer surface of the needle body may be coated or covered with a radio-opaque material to further enhance visualization of the needle body.

[0029] The tissue manipulation assembly may be manipulated and articulated through various mechanisms. One such assembly which integrates each of the functions into a singular unit may comprise a handle assembly which is connected via a tubular body to the tissue manipulation assembly. Such a handle assembly may be configured to separate from the tubular body, thus allowing for reusability of the handle. A tissue manipulation articulation control may also be positioned on the handle to provide for selective articulation of the tissue manipulation assembly.

[0030] One particular variation of the handle assembly may have handle enclosure formed in a tapered configuration which is generally symmetrically-shaped about a longitudinal axis extending from the distal end to the proximal end of the handle assembly. The symmetric feature may allow for the handle to be easily manipulated by the user regardless of the orientation of the handle enclosure during a tissue manipulation procedure.

[0031] To articulate the multiple features desirably integrated into a singular handle assembly, e.g., advancement and/or deployment of the launch tube, anchor assembly, needle assembly, articulation of the extension members and tissue manipulation assembly, etc., a specially configured locking mechanism may be located within the handle enclosure. Such a locking mechanism may generally be comprised of an outer sleeve disposed about inner sleeve where the outer sleeve has a diameter which allows for its unhindered rotational and longitudinal movement relative to the inner sleeve. A needle deployment locking control may extend radially from the outer sleeve and protrude externally from the enclosure for manipulation by the user. The outer sleeve may also define a needle assembly travel path along its length. The travel path may define the path through which the needle assembly may traverse in order to be deployed.

[0032] The needle assembly may define one or more guides protruding from the surface of the assembly which may be configured to traverse within the travel path. The inner sleeve may also define guides protruding from the surface of the inner sleeve for traversal within grooves defined in the handle enclosure. Moreover, the outer sleeve is preferably disposed rotatably about the inner sleeve such that the outer sleeve and inner sleeve are configured to selectively interlock with one another in a corresponding manner when the locking control is manipulated into specified positions.

[0033] The needle deployment assembly may be deployed through the approximation assembly by introducing the needle deployment assembly into the handle and through the

tubular body such that the needle assembly is advanced from the launch tube and into or through approximated tissue. An elongate and flexible sheath or catheter may extend removably from the needle assembly control or housing which may be interconnected via an interlock which may be adapted to allow for the securement as well as the rapid release of the
5 sheath from the housing through any number of fastening methods, e.g., threaded connection, press-fit, releasable pin, etc. The needle body, which may be configured into any one of the variations described above, may extend from the distal end of the sheath while maintaining communication between the lumen of the sheath and needle opening.

[0034] An elongate pusher may comprise a flexible wire or hypotube which is
10 translationally disposed within the sheath and movably connected within the housing. A proximally-located actuation member may be rotatably or otherwise connected to the housing to selectively actuate the translational movement of elongate pusher relative to the sheath for deploying the anchors from the needle opening. The anchor assembly may be positioned distally of the elongate pusher within the sheath for deployment from sheath. The housing
15 for the needle deployment assembly may also define an indicator window along its length to provide a visual indicator utilized to indicate the position of the elongate pusher within the sheath.

[0035] To ensure that the anchor is not prematurely ejected from the needle assembly, various interlocking features or spacing elements may be employed. For instance, adjacent
20 anchors positioned within the needle deployment assembly may be interlocked with one another via a temporary interlocking feature. Likewise, the elongate pusher and an adjacent anchor may be optionally interlocked together as well. Such an interlocking feature may enable the anchor assembly to be advanced distally as well as withdrawn proximally within the sheath and needle body in a controlled manner without the risk of inadvertently pushing
25 one or more anchors out of the needle body.

BRIEF DESCRIPTION OF THE DRAWINGS

[0036] Fig. 1A shows a side view of one variation of a tissue plication apparatus which may be used to create tissue plications and to deliver cinching or locking anchors into the
30 tissue.

[0037] Figs. 1B and 1C show detail side and perspective views, respectively, of the tissue approximation assembly of the device of Fig. 1A.

[0038] Fig. 3A shows a cross-sectional side view of an anchor delivery assembly delivering a basket-type anchor into or through a tissue fold.

[0039] Fig. 3B shows a cross-sectional side view of multiple tissue folds which may be approximated towards one another and basket anchors as being deliverable through one or 5 both tissue folds.

[0040] Fig. 4A shows a side view of one variation for a tissue engaging helix.

[0041] Fig. 4B shows a side view of another variation for a helix having a reduced pitch.

[0042] Fig. 4C shows a side view of another variation for a helix having a varied pitch.

[0043] Fig. 4D shows a side view of another variation for a helix having a piercing needle 10 positioned through the helix.

[0044] Fig. 4E shows a side view of another variation having a dual helix.

[0045] Fig. 4F shows a side view of another variation for a helix having a decreasing diameter.

[0046] Fig. 4G shows a side view of another variation for a helix combined with a grasper.

15 [0047] Figs. 5A and 5B show a hollow helix variation for deploying anchors directly through the helix.

[0048] Figs. 6A and 6B show another variation of a helix with a protective sheath which may be advanced over the helix.

20 [0049] Figs. 7A and 7B show another variation of a helix with an atraumatic member which may be advanced longitudinally through the helix.

[0050] Fig. 8 shows another variation of a helix with a blunted member which may be advanced longitudinally through the helix.

[0051] Figs. 9A and 9B show a helix which may be energized to reform into a straightened configuration, respectively, to facilitate its withdrawal from tissue.

25 [0052] Fig. 10 shows a helix variation which may be energized by a power source for use in ablating surrounding tissue.

[0053] Figs. 11A and 11B show side views of one variation of the tissue manipulation assembly having cam-actuated extension members.

[0054] Figs. 11C and 11D show detail views of the cam-actuation for the assembly of Figs. 11A and 11B.

[0055] Figs. 12A and 12B show side views of another variation of extension members which are biased towards one another.

5 [0056] Figs. 13A and 13B show side views of another variation of extension members which are actuated via a linkage assembly.

[0057] Figs. 14A to 14C show side views of another variation of extension members which are actuatable via one or more hinged arms interconnecting the extension members.

10 [0058] Figs. 15A and 15B show side views of another variation where one or more extension members are biased away from one another.

[0059] Figs. 16A and 16B show side views of another variation where one or more extension members are configured to be passively biased.

[0060] Figs. 17A and 17B show side views of another variation of extension members which are actuatable via a translatable sleeve.

15 [0061] Fig. 18 shows a side view of a tissue manipulation assembly with a lower extension member having a longer length than the upper extension member.

[0062] Fig. 19 shows a side view of another variation where one or both extension members may have tips atraumatic to tissue.

20 [0063] Figs. 20A and 20B views of a variation of lower extension members which may be configured to be actuatable.

[0064] Fig. 20C show a top view of a lower extension member which may be configured into a "C" shape.

[0065] Figs. 21A and 21B show perspective and top views of a lower extension member having one or more energize-able wires disposed thereon for tissue ablation.

25 [0066] Figs. 23A to 23C show side views of a tissue manipulation assembly which may be configured to articulate into an angle relative to the tubular body.

[0067] Figs. 24A and 24B show side and perspective detail views, respectively, of a launch tube specially configured to flex in specified planes.

[0068] Figs. 24C and 24D show side views of a portion of the launch tube having one or more coatings or coverings.

[0069] Fig. 25 shows an illustrative side view of the angle formed between the deployed needle assembly and a longitudinal axis of the tissue manipulation assembly.

5 [0070] Fig. 26A shows a partial side view of a launch tube variation having an extended launch tube distal portion for aligning the needle body for deployment.

[0071] Figs. 26B and 26C show cross-sectional views of the needle body and launch tube distal portion having various keyed cross-sectional areas.

10 [0072] Fig. 27A shows another cross-sectional view where the needle body may be keyed to the launch tube.

[0073] Fig. 27B shows a side view of the keyed needle body of Fig. 27A.

[0074] Fig. 28 shows a partial side view of an over-driven launch tube.

[0075] Figs. 29A and 29B show partial side views of an assembly having curved deployable needle assemblies.

15 [0076] Fig. 30 shows a variation where the needle body may be curved via an anvil.

[0077] Fig. 31 shows another variation in which an optical fiber or an optical fiber configured as a needle body may be advanced through a launch tube to provide visualization.

[0078] Fig. 32 shows a variation of the needle body which may be ultrasonically actuated.

[0079] Fig. 33 shows a torqueable variation of the needle body.

20 [0080] Figs 34A and 34B show needle body variations which may be configured to deploy tissue anchors via a side opening.

[0081] Figs. 35A to 35C show end views of a tissue manipulation assembly which may incorporate various colors into the device to facilitate orientation.

25 [0082] Figs. 36A to 36C show the corresponding top views, respectively, of the device of Figs. 35A to 35C.

[0083] Figs. 37A to 37D show side views of various needle bodies which may be colored, have visual markers thereon, dimpled, or have radio-opaque coatings respectively.

[0084] Figs. 38A to 38C show partial side views of variations of a handle for controlling and articulating the tissue manipulation assembly.

[0085] Figs. 39A to 39C show top, side, and cross-sectional views, respectively, of another variation of a handle having a multi-position locking and needle assembly advancement

5 system.

[0086] Fig. 39D shows an assembly view of the handle of Fig. 39A connected to the tissue manipulation assembly via a rigid or flexible tubular body or shaft.

[0087] Figs. 40A and 40B show perspective and cross-sectional views, respectively, of another variation of a handle having a reversible configuration.

10 [0088] Figs. 41A and 41B show partial cross-sectional side and detail views, respectively, of another variation of a handle having a pivotable articulation control.

[0089] Fig. 42A shows a side view of the handle of Fig. 41A having the multi-position locking and needle assembly advancement system.

15 [0090] Figs. 42B to 42D show end views of the handle of Fig. 42A and the various positions of the multi-position locking and needle assembly advancement system.

[0091] Fig. 43A shows a perspective view of one variation of the multi-position locking and needle assembly advancement system.

[0092] Figs. 43B to 43E show illustrative side views of the system of Fig. 43A configured in various locking and advancement positions.

20 [0093] Fig. 44 illustrates a side view of a needle deployment assembly which may be loaded or advanced into an approximation assembly.

[0094] Fig. 45A shows a side view of one variation of a needle deployment assembly.

[0095] Fig. 45B shows an exploded assembly of Fig. 45A in which the tubular sheath is removed to reveal the anchor assembly and elongate pusher element.

25 [0096] Figs. 46A and 46B show partial cross-sectional side views of a shuttle element advanced within the needle assembly housing.

[0097] Figs. 47A and 47B illustrate one variation of deploying the anchors using the needle assembly.

[0098] Fig. 47C illustrates a partial cross-sectional view of one variation of the needle and anchor assemblies positioned within the launch tube.

[0099] Fig. 48 shows a side view of another variation in which a manipulatable grasping needle assembly may be loaded into the approximation assembly.

5 [0100] Figs. 49A and 49B show detail side views of a variation of the manipulatable grasping needle of Fig. 48.

[0101] Figs. 50A and 50B show detail side views of another variation of the manipulatable grasping needle which may be utilized to deploy anchors.

10 [0102] Figs. 51A and 51B show partial cross-sectional views of various methods for aligning a suture through the anchor assembly within the needle assembly.

[0103] Fig. 51C shows a partial cross-sectional view of an anchor assembly variation utilizing a spacer between adjacent anchors within the needle assembly.

15 [0104] Figs. 52A and 52B show perspective detail views of unexpanded anchors having interlocking features on one or more of the collars for temporarily interlocking the anchors and/or elongate pusher to one another.

[0105] Fig. 52C shows a detail perspective view of a curved interlocking feature which may be integrated on the distal end of the elongate pusher.

[0106] Figs. 53A and 53B show another variation of an interlocking feature which may be integrated into one or more anchors.

20 [0107] Figs. 54A to 54C show a curved-tab locking feature variation which may be utilized in deploying one or more anchors.

[0108] Figs. 55A to 55C show an interlocking feature variation which may be utilized in deploying one or more anchors.

25 [0109] Figs. 56A to 56C show a tabbed locking feature variation which may be utilized in deploying one or more anchors.

[0110] Figs. 57A to 57C show a pin and groove locking feature variation which may be utilized in deploying one or more anchors.

[0111] Figs. 58A to 58C show a rotational coil locking feature variation which may be utilized in deploying one or more anchors.

[0112] Figs. 59A to 59C show an electrolytic joint locking feature variation which may be utilized in deploying one or more anchors.

[0113] Figs. 60A to 60C show a ball-groove locking feature variation which may be utilized in deploying one or more anchors.

5 [0114] Figs. 61A to 61C show a balled-joint locking feature variation which may be utilized in deploying one or more anchors.

[0115] Figs. 62A to 62C show a magnetic locking feature variation which may be utilized in deploying one or more anchors.

[0116] Fig. 63 shows a locking feature variation utilizing a cross-member.

10 [0117] Figs. 64A to 64C show various additional feature for controlling the deployment of anchors.

[0118] Fig. 65 shows a variation for deploying multiple anchors adjacently aligned within a single needle assembly.

15 [0119] Figs. 66A to 66C show partial cross-sectional side, bottom, and end views, respectively, of another variation for deploying multiple anchors in a controlled manner via corresponding retaining tabs.

DETAILED DESCRIPTION OF THE INVENTION

[0120] In creating tissue plications, a tissue plication tool having a distal tip may be advanced (transorally, transgastrically, etc.) into the stomach. The tissue may be engaged or 20 grasped and the engaged tissue may be moved to a proximal position relative to the tip of the device, thereby providing a substantially uniform plication of predetermined size. Examples of creating and forming tissue plications may be seen in further detail in U.S. Pat. App. Serial No. 10/735,030 filed December 12, 2003, which is incorporated herein by reference in its entirety.

25 [0121] In order to first create the plication within a body lumen of a patient, various methods and devices may be implemented. The anchoring and securement devices may be delivered and positioned via an endoscopic apparatus that engages a tissue wall of the gastrointestinal lumen, creates one or more tissue folds, and disposes one or more of the

anchors through the tissue fold(s). The tissue anchor(s) may be disposed through the muscularis and/or serosa layers of the gastrointestinal lumen.

[0122] Generally, in creating a plication through which a tissue anchor may be disposed within or through, a distal tip of a tissue plication apparatus may engage or grasp the tissue
5 and move the engaged tissue to a proximal position relative to the tip of the device, thereby providing a substantially uniform plication of predetermined size.

[0123] Formation of a tissue fold may be accomplished using at least two tissue contact areas that are separated by a linear or curvilinear distance, wherein the separation distance between the tissue contact points affects the length and/or depth of the fold. In operation, a
10 tissue grabbing assembly engages or grasps the tissue wall in its normal state (i.e., non-folded and substantially flat), thus providing a first tissue contact area. The first tissue contact area then is moved to a position proximal of a second tissue contact area to form the tissue fold. The tissue anchor assembly then may be extended across the tissue fold at the second tissue contact area. Optionally, a third tissue contact point may be established such that, upon
15 formation of the tissue fold, the second and third tissue contact areas are disposed on opposing sides of the tissue fold, thereby providing backside stabilization during extension of the anchor assembly across the tissue fold from the second tissue contact area.

[0124] The first tissue contact area may be utilized to engage and then stretch or rotate the tissue wall over the second tissue contact area to form the tissue fold. The tissue fold may
20 then be articulated to a position where a portion of the tissue fold overlies the second tissue contact area at an orientation that is substantially normal to the tissue fold. A tissue anchor may then be delivered across the tissue fold at or near the second tissue contact area. An apparatus in particular which is particularly suited to deliver the anchoring and securement devices described herein may be seen in further detail in co-pending U.S. Pat. App. Serial No.
25 10/840,950 filed May 7, 2004, which is incorporated herein by reference in its entirety.

[0125] An illustrative side view of a tissue plication assembly **10** which may be utilized with the tissue anchors described herein is shown in Fig. 1A. The plication assembly **10** generally comprises a catheter or tubular body **12** which may be configured to be sufficiently flexible for advancement into a body lumen, e.g., transorally, percutaneously,
30 laparoscopically, etc. Tubular body **12** may be configured to be torqueable through various methods, e.g., utilizing a braided tubular construction, such that when handle **16** is manipulated and rotated by a practitioner from outside the body, the torquing force is

transmitted along body 12 such that the distal end of body 12 is rotated in a corresponding manner.

[0126] Tissue manipulation assembly 14 is located at the distal end of tubular body 12 and is generally used to contact and form the tissue plication, as mentioned above. Fig. 1B shows 5 an illustrative detail side view and Fig. 1C shows a perspective view of tissue manipulation assembly 14 which shows launch tube 18 extending from the distal end of body 12 and in-between the arms of upper extension member or bail 20. Launch tube 18 may define launch tube opening 24 and may be pivotally connected near or at its distal end via hinge or pivot 22 to the distal end of upper bail 20. Lower extension member or bail 26 may similarly extend 10 from the distal end of body 12 in a longitudinal direction substantially parallel to upper bail 20. Upper bail 20 and lower bail 26 need not be completely parallel so long as an open space between upper bail 20 and lower bail 26 is sufficiently large enough to accommodate the drawing of several layers of tissue between the two members.

[0127] Upper bail 20 is shown in the figure as an open looped member and lower bail 26 is 15 shown as a solid member; however, this is intended to be merely illustrative and either or both members may be configured as looped or solid members. Tissue acquisition member 28 may be an elongate member, e.g., a wire, hypotube, etc., which terminates at a tissue grasper or engager 30, in this example a helically-shaped member, configured to be reversibly rotatable for advancement into the tissue for the purpose of grasping or acquiring a region of 20 tissue to be formed into a plication. Tissue acquisition member 28 may extend distally from handle 16 through body 12 and distally between upper bail 20 and lower bail 26. Acquisition member 28 may also be translatable and rotatable within body 12 such that tissue engager 30 is able to translate longitudinally between upper bail 20 and lower bail 26. To support the longitudinal and rotational movement of acquisition member 28, an optional guide or linear 25 bearing 32 may be connected to upper 20 or lower bail 26 to freely slide thereon. Guide 32 may also be slidably connected to acquisition member 28 such that the longitudinal motion of acquisition member 28 is supported by guide 32.

[0128] An example of a tissue plication procedure is seen in Figs. 2A to 2D for delivering and placing a tissue anchor and is disclosed in further detail in co-pending U.S. Pat. App. 30 Serial No. 10/840,950 filed May 7, 2004, which has been incorporated by reference above. Tissue manipulation assembly 14, as seen in Fig. 2A, may be advanced into a body lumen such as the stomach and positioned adjacent to a region of tissue wall 40 to be plicated.

During advancement, launch tube **18** may be configured in a delivery profile such that tube **18** is disposed within or between the arms of upper bail **20** to present a relatively small profile.

[0129] Once tissue manipulation assembly **14** has been desirably positioned relative to tissue wall **40**, tissue grasper or engager **30** may be advanced distally such that tissue grasper or engager **30** comes into contact with tissue wall **40** at acquisition location or point **42**. As tissue grasper or engager **30** is distally advanced relative to body **12**, guide **32**, if utilized, may slide distally along with tissue grasper or engager **30** to aid in stabilizing the grasper. If a helically-shaped tissue grasper or engager **30** is utilized, as illustrated in Fig. 2B, it may be rotated from its proximal end at handle **16** and advanced distally until the tissue at point **42** has been firmly engaged by tissue grasper or engager **30**. This may require advancement of tissue grasper or engager **30** through the mucosal layer and at least into or through the underlying muscularis layer and possibly into or through the serosa layer.

[0130] The grasped tissue may then be pulled proximally between upper **20** and lower bails **26** via tissue grasper or engager **30** such that the acquired tissue is drawn into a tissue fold **44**, as seen in Fig. 2C. As tissue grasper or engager **30** is withdrawn proximally relative to body **12**, guide **32** may also slide proximally to aid in stabilizing the device especially when drawing the tissue fold **44**.

[0131] Once the tissue fold **44** has been formed, launch tube **18** may be advanced from its proximal end at handle **16** such that a portion **46** of launch tube **18**, which extends distally from body **12**, is forced to rotate at hinge or pivot **22** and reconfigure itself such portion **46** forms a curved or arcuate shape that positions launch tube opening **24** perpendicularly relative to a longitudinal axis of body **12** and/or bail members **20**, **26**. Launch tube **18**, or at least portion **46** of launch tube **18**, is preferably fabricated from a highly flexible material or it may be fabricated, e.g., from Nitinol tubing material which is adapted to flex, e.g., via circumferential slots, to permit bending. Alternatively, assembly **14** may be configured such that launch tube **18** is reconfigured simultaneously with the proximal withdrawal of tissue grasper or engager **30** and acquired tissue **44**.

[0132] As discussed above, the tissue wall of a body lumen, such as the stomach, typically comprises an inner mucosal layer, connective tissue, the muscularis layer and the serosa layer. To obtain a durable purchase, e.g., in performing a stomach reduction procedure, the staples or anchors used to achieve reduction of the body lumen are preferably engaged at

least through or at the muscularis tissue layer, and more preferably, the serosa layer. Advantageously, stretching of tissue fold 44 between bail members 20, 26 permits an anchor to be ejected through both the muscularis and serosa layers, thus enabling durable gastrointestinal tissue approximation.

5 [0133] As shown in Fig. 2D, once launch tube opening 24 has been desirably positioned relative to the tissue fold 44, needle assembly 48 may be advanced through launch tube 18 via manipulation from its proximal end at handle 16 to pierce preferably through a dual serosa layer through tissue fold 44. Needle assembly 48 is preferably a hollow tubular needle through which one or several tissue anchors may be delivered through and ejected from in
10 securing the tissue fold 44, as further described below.

[0134] Because needle assembly 48 penetrates the tissue wall twice, it exits within the body lumen, thus reducing the potential for injury to surrounding organs. A detail cross-sectional view is shown in Fig. 3A of anchor delivery assembly 50 in proximity to tissue fold F. In this example, tissue fold F may comprise a plication of tissue created using the apparatus
15 described herein or any other tool configured to create such a tissue plication. Tissue fold F may be disposed within a gastrointestinal lumen, such as the stomach, where tissue wall W may define the outer or serosal layer of the stomach. Anchor delivery assembly may generally comprise launch tube 18 and needle assembly 48 slidably disposed within launch tube lumen 52. Needle assembly 48 is generally comprised of needle 54, which is preferably
20 a hollow needle having a tapered or sharpened distal end to facilitate its travel into and/or through the tissue. Other parts of the assembly, such as upper and lower bail members 20, 26, respectively, and tissue acquisition member 28 have been omitted from these figures only for clarity.

[0135] Once launch tube 18 has been desirably positioned with respect to tissue fold F,
25 needle 54 may be urged or pushed into or through tissue fold F via delivery push tube or catheter 64 from its proximal end preferably located within handle 16. Delivery push tube or catheter 64 may comprise an elongate flexible tubular member to which needle 54 is connected or attached via joint 62. Alternatively, needle 54 and delivery push tube 64 may be integrally formed from a singular tubular member. Needle 54 may define needle lumen 56
30 through which basket anchor assembly 66, i.e., distal anchor 58 and/or proximal anchor 60 may be situated during deployment and positioning of the assembly. A single suture or flexible element 76 (or multiple suture elements) may connect proximal anchor 60 and distal

anchor **58** to one another. For instance, element **76** may comprise various materials such as monofilament, multifilament, or any other conventional suture material, elastic or elastomeric materials, e.g., rubber, etc.

[0136] Alternatively, metals which are biocompatible may also be utilized for suture materials. For instance, sutures may be made from metals such as Nitinol, stainless steels, Titanium, etc., provided that they are formed suitably thin and flexible. Using metallic sutures with the anchoring mechanisms described herein may additionally provide several benefits. For example, use of metallic suture material may decrease any possibilities of suture failure due to inadvertent cutting or shearing of the suture, it may provide a suture better able to withstand the acidic and basic environment of the gastrointestinal system, and it may also enhance imaging of the suture and anchor assembly if examined under conventional imaging systems such as X-rays, fluoroscopes, MRI, etc. As used herein, suture **76** may encompass any of these materials or any other suitable material which is also biocompatible.

[0137] Needle **54** may optionally define a needle slot along its length to allow suture **76** to pass freely within and out of needle **54** when distal anchor **58** is ejected from needle lumen **56**. Alternatively, rather than utilizing a needle slot, needle **54** may define a solid structure with suture **76** being passed into and through needle lumen **56** via the distal opening of needle **54**.

[0138] The proximal end of suture **76** may pass slidingly through proximal anchor **60** to terminate in a suture loop. The proximal end of suture **76** may terminate proximally of the apparatus **10** within control handle **16**, proximally of control handle **16**, or at some point distally of control handle **16**. In this variation, a suture loop may be provided to allow for a grasping or hooking tool to temporarily hold the suture loop for facilitating the cinching of proximal **60** and distal **58** anchors towards one another for retaining a configuration of tissue fold **F**, as described in further detail in U.S. Pat. App. Serial No. 10/840,950, which has been incorporated by reference above.

[0139] After needle assembly **48** has been pushed distally out through launch tube opening **24** and penetrated into and/or through tissue fold **F**, as shown in Fig. 3A, anchor pushrod or member **78** may be actuated also via its proximal end to eject distal anchor **58**. Once distal anchor **58** has been ejected distally of tissue fold **F**, needle **54** may be retracted back through tissue fold **F** by either retracting needle **54** back within launch tube lumen **18** or by withdrawing the entire anchor delivery assembly **50** proximally relative to tissue fold **F**.

[0140] Once needle 54 has been retracted, proximal anchor 60 may then be ejected from launch tube 18 on a proximal side of tissue fold F. With both anchors 58, 60 disposed externally of launch tube 18 and suture 76 connecting the two, proximal anchor 60 may be urged into contact against tissue fold F, as shown in Fig. 3B. As proximal anchor 60 is urged 5 against tissue fold F, proximal anchor 60 or a portion of suture 76 may be configured to provide any number of directionally translatable locking mechanisms which provide for movement of an anchor along suture 76 in a first direction and preferably locks, inhibits, or prevents the reverse movement of the anchor back along suture 76. In other alternatives, the anchors may simply be delivered through various elongate hollow tubular members, e.g., a 10 catheter, trocars, etc.

[0141] The basket anchors may comprise various configurations suitable for implantation within a body lumen. Basket anchors are preferably reconfigurable from a low profile delivery configuration to a radially expanded deployment configuration in which a number of struts, arms, or mesh elements may radially extend once released from launch tube 18 or 15 needle 54. Materials having shape memory or superelastic characteristics or which are biased to reconfigure when unconstrained are preferably used, e.g., spring stainless steels, Ni-Ti alloys such as Nitinol, etc. In Figs. 3A and 3B, each of the basket anchor 58, 60 is illustrated as having a number of reconfigurable struts or arm members 72 extending between distal collar 68 and proximal collar 70; however, this is intended only to be illustrative and suitable 20 basket anchors are not intended to be limited to baskets only having struts or arms. Examples of suitable anchors are further described in detail in U.S. Pat. App. Serial No. 10/612,170, which has already been incorporated herein above.

[0142] Fig. 3B shows distal basket anchor 58 delivered through tissue fold F via needle 54 and launch tube 18. As above, the other parts of the plication assembly, such as upper and 25 lower bail members 20, 26, respectively, and tissue acquisition member 28 have been omitted from these figures only for clarity.

[0143] Fig. 3B shows one variation where a single fold F may be secured between proximal anchor 60 and distal anchor 58'. As seen, basket anchor 58' has been urged or ejected from needle 54 and is shown in its radially expanded profile for placement against the 30 tissue surface. In such a case, a terminal end of suture 76 may be anchored within the distal collar of anchor 58' and routed through tissue fold F and through, or at least partially through, proximal anchor 60, where suture 76 may be cinched or locked proximally of,

within, or at proximal anchor 60 via any number of cinching mechanisms. Proximal anchor 60 is also shown in a radially expanded profile contacting tissue fold F along tissue contact region 74. Locking or cinching of suture 76 proximally of proximal anchor 60 enables the adequate securement of tissue fold F.

5 [0144] Various examples of cinching devices and methods which may be utilized with the tools and devices herein are described in further detail in U.S. Pat. App. Serial No. 10/840,950 filed May 7, 2004, which has been incorporated herein above.

[0145] If additional tissue folds are plicated for securement, distal basket anchor 58 may be disposed distally of at least one additional tissue fold F', as shown in Fig. 3B, while proximal anchor 60 may be disposed proximally of tissue fold F. As above, suture 76 may be similarly affixed within distal anchor 58 and routed through proximal anchor 60, where suture 76 may be cinched or locked via proximal anchor 60, as necessary. If tissue folds F and F' are to be positioned into apposition with one another, distal basket anchor 58 and proximal anchor 60 may be approximated towards one another. As described above, proximal anchor 60 is preferably configured to allow suture 76 to pass freely therethrough during the anchor approximation. However, proximal anchor 60 is also preferably configured to prevent or inhibit the reverse translation of suture 76 through proximal anchor 60 by enabling unidirectional travel of anchor 60 over suture 76. This cinching feature thereby allows for the automated locking of anchors 58, 60 relative to one another during anchor approximation.

20 [0146] With respect to the anchor assemblies described herein, the types of anchors shown and described are intended to be illustrative and are not limited to the variations shown. For instance, several of the tissue anchor variations are shown as "T"-type anchors while other variations are shown as reconfigurable "basket"-type anchors, which may generally comprise a number of configurable struts or legs extending between at least two collars or support members. Other variations of these or other types of anchors are also contemplated for use in an anchor assembly. Moreover, a single type of anchor may be used exclusively in an anchor assembly; alternatively, a combination of different anchor types may be used in an anchor assembly. Furthermore, the different types of cinching or locking mechanisms are not intended to be limited to any of the particular variations shown and described but may be utilized in any of the combinations or varying types of anchors as practicable.

[0147] TISSUE ENGAGEMENT TOOLS

- [0148] As mentioned above, tissue acquisition member **28** may be an elongate member, e.g., a wire, hypotube, etc., which has a tissue grasper or engager **30** attached or integrally formed at its distal end for grasping or engaging the tissue. In one variation, the tissue
5 grasper may be formed as a helix having a uniform outer diameter with a constant pitch, as shown in the detail view of helix **80** in Fig. 4A. Helix **80** may be attached to acquisition member **28** via any suitable fastening method, e.g., adhesives, solder, etc. Alternatively, helix **80** may be integrally formed from the distal portion of acquisition member **28** by winding or coiling the distal portion in a helix configuration.
- 10 [0149] In another variation, the tissue grasper may be formed into a helix **82** having a pitch which is greater relatively than helix **80** such that the variation of helix **82** has relatively fewer windings, as shown in Fig. 4B. Alternatively, a multi-pitch helix **84** may be formed having one or more regions with varying pitch along a length of helix **84**. As seen in fig. 4C, multi-pitch helix **84** may have a distal portion **86** having a relatively lower pitch and a
15 proximal portion having a relatively higher pitch **88**. A single helix having regions of varied pitch may be utilized to initially pierce and grasp tissue onto the region of lower pitch **86**; when the helix **84** is rotated to advance into or through the tissue, the pierced tissue advanced over helix **84** may be wound upon the region of higher pitch **88** where the tissue may be better adhered to helix **84** by the tighter windings.
- 20 [0150] Another variation of a tissue grasper may be seen in Fig. 4D. In this variation, helix **90** may have a piercing needle **92** extending through the center and protruding distally of helix **90** to facilitate piercing of the tissue and initial entry of helix **90** into the tissue. Yet another variation is shown in Fig. 4E where a dual-helix variation may be utilized. Here, first helix **94** may be inter-wound with second helix **96** in a dual helix configuration.
- 25 [0151] Another variation is shown in Fig. 4F in which helix **98** may define a helix having a decreasing diameter distally of acquisition member **28**. In this variation or any of the variations of the helix described herein, certain aspects of one helix variation may be utilized in any number of combinations with any of the other aspects of other variations as practicable. For instance, the variation of the dual-helix in Fig. 4E may also comprise the
30 piercing needle **92** of Fig. 4D. This variation may also include aspects of the helix **84** having varying regions of differing pitch, as shown in Fig. 4C, and so on in any number of combinations as practicable.

[0152] Fig. 4G shows yet another variation in dual grasping assembly 100 where helix 102 may utilize articulatable grasping jaw members 104, 106 in combination with the helix 102. As the helix 102 initially pierces and rotatingly retains the tissue, acquisition member 28 may be withdrawn proximally to pull the tissue between jaws 104, 106, which may then be 5 articulated to further clamp onto the tissue to ensure tissue retention by assembly 100. Articulatable jaws 104, 106 may optionally define serrations or teeth 108, 110 upon one or more of the jaw members 104, 106 in contact against the tissue to further facilitate tissue retention.

[0153] In addition to the various configurations, the tissue grasper may be further utilized 10 to retain tissue via tissue anchors. Figs. 5A and 5B show side views of a helix variation 120 which may be completely or partially hollow for engaging tissue. One or more deployable anchors 124 may be positioned within or advanced through hollow helix 120. With at least the distal portion or tip of hollow helix 120 pierced into or through the tissue T, as shown in Fig. 5A, tissue anchor 124 may be urged from opening 122 defined in hollow helix 120 15 through any number of methods, e.g., an elongate pusher. Once tissue anchor 124 has been deployed or ejected from distal opening 122, helix 120 may be withdrawn proximally partially or entirely from tissue T while leaving anchor 124 behind. Anchor 124 may be connected to suture 126 which may be routed through or connected to helix 120 such that creation of a tissue fold from tissue T may be achieved by pulling anchor 124 proximally, as 20 shown in Fig. 5B. After the tissue T has been desirably manipulated or folded, suture 126 may be released from helix 120 so that helix 120 may be withdrawn from the region.

[0154] During manipulation of the tissue and articulation of the helix within the patient's body, e.g., within the stomach, optional measures may be taken to prevent the helix from inadvertently damaging any surrounding tissue. One variation may be seen in the detail side 25 view of sheathed helix assembly 130 in Fig. 6A. The sheath 132 may completely or partially cover helix 80 to present an atraumatic surface to the surrounding tissue when the helix 80 is not in use within the patient's body, as shown in Fig. 6B. Additionally, sheath 132 may also be utilized outside the patient to protect helix 80 when handled for transport or during preparation of the device for use. Sheath 132 may be optionally advanced distally over helix 30 80 or helix 80 may be withdrawn proximally into sheath 132.

[0155] Another variation for providing an atraumatic surface for the helix to surrounding tissue may be seen in Figs. 7A and 7B. As shown, helix assembly 140 may have an insertion

member **142** which defines anatraumatic distal end **144** advanced through the center of helix **80**. When the helix **80** is not in use, insertion member **142** may be advanced distally within helix **80** to the distal end of helix **80** such that inadvertent tissue piercing is prevented by member **142**.

5 [0156] Yet another variation is shown in Fig. 8 in which blunted element **150** may be advanced through the center of helix **80** via an elongate delivery member **152**. When helix **80** is utilized, member **150** may be withdrawn proximally relative to helix **80** in the same manner as helix assembly **140** above.

[0157] Another variation of the helix assembly is shown in the illustrative side views of
10 Figs. 9A and 9B. In this variation, reconfigurable helix **160** may be configured to have a configuration for facilitating its advancement into tissue or for withdrawing the helix **160** from tissue. Fig. 9A shows reconfigurable helix **160** is seen in its coiled configuration for piercing and adhering tissue thereto. Helix **160** may be fabricated from a shape memory alloy, such as Nitinol, to have a relaxed configuration of a helix, as shown in Fig. 9A. Once
15 energy is applied, helix **160** may be configured to reconfigure itself into a straightened configuration **160'**, as shown in Fig. 9B, to facilitate its removal from the tissue. Helix **160** may be electrically connected via electrically conductive acquisition member **162** and connection or wires **164** to a power source **166**. If helix **160** were advanced into tissue in its coiled configuration, withdrawal of the helix **160** may be quickly effected by applying energy
20 to helix **160** via power source **166**. Alternatively, power may be applied to helix **160** such that its straightened configuration **160'** takes shape to facilitate piercing into tissue. Power may then be removed such that helix **160** conforms into its coiled configuration once in the tissue such that the tissue adheres to the helix **160**.

[0158] In the reconfigurable helix **160** above, the length of helix **160** may be insulated to
25 shield the surrounding tissue from the applied energy. However, another variation of the tissue grasping member may be seen in energizable helix **170** in Fig. 10. In this variation, the entire length or a partial length of helix **170** may be uninsulated such that when helix **170** is energized through electrical connection **174** and through electrically conductive acquisition member **172** via power source **176**, the uninsulated portion or portions of energized helix **170**
30 may be utilized to contact and ablate selected regions of tissue. For instance, prior to or after a tissue fold has been formed, helix **170** may be energized to ablate the areas of the tissue

which are to be approximated towards one another to facilitate tissue adhesion between selected regions of tissue folds.

[0159] As mentioned above, in this variation or any of the variations of the helix, certain aspects of one helix variation may be utilized in any number of combinations with any of the other aspects of other variations as practicable.

[0160] EXTENSION MEMBERS

[0161] In addition to the variations of the tissue grasper or helix, the upper and/or lower extension members or bails may also be configured into a variety of embodiments which may be utilized in any number of combinations with any of the helix variations as practicable.

10 Although the upper and lower extension members or bails may be maintained rigidly relative to one another, the upper and/or lower extension members may be alternatively configured to articulate from a closed to an open configuration or conversely from an open to a closed configuration for facilitating manipulation or stabilization of tissue drawn between the bail members.

15 [0162] In operation, once the selected region of tissue has been acquired by the tissue grasper 30, the obtained tissue may be proximally withdrawn between the bail members, which may act as stabilizers for the tissue. To accommodate large portions of grasped tissue between the bail members, one or both bail members may be articulated or urged to open apart from one another to allow the tissue to enter and become positioned between the bail members. One or both bail members may then be articulated or urged to clamp or squeeze the tissue fold between the bail members to facilitate stabilization of the tissue fold for tissue manipulation and/or anchor deployment and/or any other procedure to be undertaken.

[0163] One such articulatable extension assembly may be seen in the side views of Figs. 11A and 11B. Other features such as the launch tube and tubular body have been omitted merely for the sake of clarity for the following illustrations. As seen in Fig. 11A, upper extension member 182 and lower extension member 184 of active extension assembly 180 may be configured to have an open or spread configuration relative to one another when guide or linear bearing 186 is positioned distally along upper extension member 182. Linear bearing 186 may be configured to slide freely along upper extension member 182 when urged by acquisition member 28 distally or proximally. Rather than having linear bearing 186 slide along upper extension member 182, it may be configured alternatively to slide along lower extension member 184.

[0164] With tissue grasper 30 and acquisition member 28 distally protruding from extension members 182, 184, as shown in Fig. 11A, the desired region of tissue may be acquired by rotating tissue grasper 30 into the tissue. Once tissue has been acquired by tissue grasper 30, the tissue may be pulled between the opened extension members 182, 184 by

5 proximally withdrawing tissue grasper 30 and linear bearing 186 may be forced proximally over upper extension member 182, as shown in the detail view of Fig. 11C. One or more projections or pistons 188 may protrude proximally from linear bearing 186 such that one or more of these projections 188 comes into contact with actuation lever or member 192, as shown in Fig. 11D, which may be located proximally of extension members 182, 184 and
10 connected in a pivoting relationship with lower extension member 184 about pivot 190. As linear bearing 186 is urged proximally and projection 188 presses against actuation lever 192, lower extension member 184 may be rotated about pivot 190 such that lower extension member 184 is urged towards upper extension member 182 to securely clamp onto and retain any tissue positioned between the extension members 182, 184.

15 [0165] Another articulatable extension assembly may be seen in assembly 200 in the side views of Figs. 12A and 12B. In this variation, upper extension member 202 may project distally opposite lower extension member 204 which may be biased to close towards upper extension member 202. When tissue grasper 30 is advanced to engage tissue, as shown in Fig. 12A, linear bearing 206 may be urged distally along upper extension member 202 via
20 acquisition member 28 such that lower extension member 204 is forced or wedged away from upper extension member 202. Once the tissue is engaged and withdrawn proximally, linear bearing 206 may be pulled proximally while sliding along lower member 204 and allowing lower member 204 to spring back towards upper member 202 and over any tissue positioned therebetween, as shown in Fig. 12B.

25 [0166] Another articulatable extension assembly is shown in the side views of extension assembly 210 of Figs. 13A and 13B. In this variation, upper extension member 212 and/or lower extension member 214 may be connected to linkage assembly 218 located proximally of the extension members 212, 214. Linkage assembly 218 may be manipulated via any number of control mechanisms such as control wires to urge extension members 212, 214
30 between open and closed configurations. Alternatively, linkage assembly 218 may be configured to open or close upon the proximal or distal advancement of linear bearing 216 relative to linkage assembly.

[0167] Figs. 14A to 14C show side views of another variation in extension assembly **220** where upper and lower extension members **222**, **224** are articulatable between open and closed configurations via a pivoting arm or member **234** interconnecting the two. In this example, a first end of pivoting arm **234** may be in a pivoting connection at pivot **228** with linear bearing **226**, which may slide translationally along upper member **222**. A second end of pivoting arm **234** may also be in a pivoting connection with lower extension member **224** at pivot **230**, which may remain fixed to lower member **224**. Acquisition member **28** may also be in a third pivoting connection with pivoting arm **234** at pivot **232**, which may also be configured to allow for the linear translation of acquisition member therethrough.

[0168] In operation, when acquisition member **28** and tissue grasper **30** is advanced distally, as shown in Fig. 14A, both upper and lower extension members **222**, **224** are in a closed configuration with linear bearing **226** being advanced distally along upper extension member **222**. As tissue grasper **30** is withdrawn proximally between extension members **222**, **224**, pivoting arm **234** may be pivoted about fixed pivot **230** on lower member **224** while upper member **222** is urged into an open configuration as linear bearing **226** is urged proximally over upper member **222**, as shown in Fig. 14B. This expanded or open configuration allows for the positioning of large portions of tissue to be drawn between the extension members **222**, **224** for stabilization. Fig. 14C shows tissue grasper **30** as having been further withdrawn and linear bearing **226** urged proximally such that upper member **222** is urged back into a closed configuration relative to lower member **224**. The closing of extension members **222**, **224** allows for the members to further clamp upon any tissue therebetween for further stabilization of the tissue.

[0169] Figs. 15A and 15B show another alternative in active extension assembly **240**. In this variation, upper extension member **242** may be biased to extend away from lower extension member **244**. As shown in Fig. 15A, upper extension member **242** may remain in an open configuration relative to lower member **244** for receiving tissue therebetween. In this variation, biased upper member **242** may be urged into a closed configuration by pivoting the launch tube **18** about pivot **246**, which may be located along upper member **242**. As launch tube **18** is pivoted into an anchor deployment configuration, the pivoting action may urge upper member **242** towards lower member **244** to clamp upon any tissue therebetween.

[0170] Figs. 16A and 16B show yet another alternative in assembly **250** where upper extension member **252** and/or lower extension member **254** may be passively urged into an

open configuration. In this example, lower extension member 254 is shown as being flexed from a relaxed configuration in Fig. 16A to a flexed configuration in Fig. 16B. As linear bearing 256 is withdrawn proximally, any tissue engaged to tissue grasper 30 may urge lower extension member 254 from its normal position 258 to its flexed and opened position.

5 Accordingly, lower extension member 254 and/or upper extension member 252 may be made from a relatively flexible plastic or metallic material, e.g., Nitinol, spring stainless steel, etc. When tissue is removed from between the extension members 252, 254, lower extension member 254 may return to its normal configuration 258.

[0171] Figs. 17A and 17B show side views of another assembly 260 in which upper and/or 10 lower extension members 262, 264 may be biased or configured to flex away from one another, as shown in Fig. 17A. Once linear bearing 266 and tissue grasper 30 has been retracted, an outer sleeve 268 slidably disposed over tubular body 12 may be pushed distally such that sleeve 268 is slid over at least a proximal portion of extension members 262, 264 15 such that they are urged towards one another into a closed configuration onto tissue which may be present therebetween, as shown in Fig. 17B.

[0172] Aside from features such as articulation of the extension members, the extension members themselves may be modified. For instance, Fig. 18 shows a side view of extension assembly 270 where lower extension member 274 may be extended in length relative to upper extension member 272. The length of lower extension member 274 may be varied 20 depending upon the desired result. Alternatively, upper extension member 272 may be shortened relative to lower extension member 274. The lengthening of lower extension member 274 may be utilized to present a more stable platform for tissue approximated between the extension members 262, 264.

[0173] Another alternative for modifying the extension members is seen in the side view of 25 Fig. 19 in extension assembly 280. In this example, one or both extension members 282, 284 may be configured to have atraumatic blunted ends 286 which may be further configured to be flexible to allow tissue to slide over the ends. Moreover, atraumatic ends 286 may be configured in a variety of ways provided that an atraumatic surface or feature is presented to the tissue.

30 [0174] In addition to atraumatic features, the lower extension member of the tissue manipulation assembly may be varied as well. For example, as the needle assembly and tissue anchors are deployed from the launch tube, typically from the upper extension

member, it is preferable to have sufficient clearance with respect to the lower extension member so that unhindered deployment is facilitated. One method for ensuring unhindered deployment is via a lower extension member having a split opening defined near or at its distal end, as shown in the perspective view of tissue manipulation assembly 290 in Fig. 20A.

- 5 Such a split may allow for any deployed anchors or suture an opening through which to be released from assembly 290.

[0175] Additionally, the jaws which define the opening may be articulatable as well relative to lower extension member 294. As shown in the bottom view of Fig. 20B, articulatable lower extension assembly 292 may have one or both jaw members 296, 298 10 articulatable via pivots 300, 302, respectively, relative to lower extension member 294 such that one or both jaw members 296, 298 are able to be moved between a closed configuration, as shown in Fig. 20A, and an open configuration, as shown in Fig. 20B. This variation in assembly 290 may allow for any needle or anchor assemblies to easily clear lower extension member 294.

- 15 [0176] Another variation of lower extension member 304 is shown in the bottom view of Fig. 20C. In this variation, an enclosing jaw member 306 may extend from lower extension member 304 such that an opening 308 along either side of extension member 304 is created. Such an opening 308 may create a “C”-shaped lower extension member 304 which may facilitate needle and anchor deployment from the tissue manipulation assembly.

- 20 [0177] Another variation of a tissue manipulation assembly 310 may be seen in the illustrative partial perspective view of Fig. 21A. In addition to articulation or release features, one or both extension members may be utilized to selectively ablate regions of tissue. Assembly 310 for instance may have a tissue ablation assembly 312 integrated into the lower extension member 320. Such a tissue ablation assembly 312, as seen in the top 25 view of Fig. 21B, may incorporate one or more wires or electrically conductive elements 318 upon lower extension member 320 to create a tissue ablation region. The lower extension member 320 may be fabricated from a non-conductive material upon which wires 318 may be integrated. Alternatively, the entire lower member 320 may be electrically conductive with regions selectively insulated leaving non-insulated areas to create ablation regions 318. The 30 wires or regions 318 may be electrically connected via wires 314 to power source 316, which may provide various forms of energy for tissue ablation, e.g., radio-frequency, microwave, etc.

[0178] One example for use of the ablative tissue manipulation assembly may be seen in Figs. 22A to 22E where tissue approximation assembly 330 may be seen with tissue manipulation assembly 14 advanced through an optional shape-lockable overtube 332. Ablation region 318 is integrated into the lower extension member 320 of the tissue manipulation assembly, as above. Alternatively, region 318 may, for example, comprise an abrasive surface disposed on lower extension member 320. Alternatively, the lower extension member 320 may comprise an ablation electrode for injuring mucosal tissue.

[0179] As seen in Fig. 22B, when tissue wall 40 is folded between the extension members of assembly 14, target mucosal tissue 334 contacts lower extension member 320 as well as ablation region 318. Passive or active actuation of ablation region 318 may then injure and/or remove the target mucosal tissue 334. As further seen in Fig. 22C, this procedure may be repeated at one or more additional tissue folds 336, 338 that may then be approximated together, as in Fig. 22D. The contacting injured regions of mucosal tissue promote healing and fusion 340 of the approximated folds, as in Fig. 22E.

[0180] Aside from variations on aspects of the tissue manipulation assembly, the entire assembly may also be modified to adjust the tissue manipulation assembly position relative to the tubular body upon which the assembly is attachable. Fig. 23A shows a distal portion of tubular body 12 and tissue manipulation assembly 14 connected thereto. While tubular body 12 may comprise a rigid or flexible length, tissue manipulation assembly 14 may be further configured to articulate relative to tubular body 12, as shown in Fig. 23B, to further enhance the maneuverability and manipulation capabilities of tissue manipulation assembly 14. In one example, assembly 14 may be connected to tubular body 12 via a hinged or segmented articulatable portion 350, shown in the detail Fig. 23C, which allows assembly 14 to be reconfigured from a low-profile configuration straightened relative to tubular body 12 to an articulated configuration where assembly 14 forms an angle, α , relative to tubular body 12. The angle, α , may range anywhere from 180° to -180° depending upon the desired level of articulation. Articulatable portion 350 may be configured to allow assembly 14 to become articulated in a single plane or it may also be configured to allow a full range of motion unconstrained to a single plane relative to tubular body 12. Articulation of assembly 14 may be accomplished any number of various methods, e.g., control wires.

[0181] Any of the variations of the tissue manipulation assemblies or aspects of various features of the tissue manipulation assemblies is intended to be utilized in any number of

combinations with other aspects of other variations as practicable. Moreover, any of the variations relating to the tissue manipulation assemblies may also be used in any number of combinations, as practicable, with the helix variations described above, if so desired.

[0182] LAUNCH TUBE

5 [0183] An illustrative side view of a partial launch tube **18** configured for anchor deployment may be seen in Fig. 24A. Launch tube **18** is typically configured to partially translate relative to the tissue manipulation assembly such that a distal portion of the launch tube **18** may be articulated perpendicularly to the tissue to be pierced. Launch tube **18** may be made from a variety of flexible materials which are flexible yet sufficiently strong to
10 withstand repeated flexing of the tube.

[0184] Fig. 24B shows a portion **360** of launch tube **18** which may be fabricated from a metal such as Nitinol, stainless steel, titanium, etc. To facilitate the flexure of tube **18**, such a tube may be selectively scored or cut to enhance the directional flexibility of the tube **18**. Accordingly, in one variation, a plurality of circumferential cuts or slits **366** may be made in
15 the portion of launch tube **18** which is flexed. Cuts **366** may extend between one or more lengths or spines **362**, **364** of uncut tube material which may extend over the length of the flexible portion. These spines **362**, **364** in combination with the cuts **366** may facilitate the directional flexibility or bending of launch tube **18** in a singular bending plane. Cuts **366**
20 may be made along the launch tube **18** using any number methods, e.g., mechanical cutting, laser cutting, chemical etching, etc.

[0185] Another variation of launch tube **18** is shown in the partial views of Figs. 24C and 24D. Launch tube wall **368** may be seen in Fig. 24C with an optional inner covering or coating **370** while Fig. 24D shows another variation of launch tube wall **368** with an optional additional outer coating **372**. Inner covering or coating **370** may be comprised of a lubricious material, e.g., PTFE, etc., to facilitate the ease with which the needle assembly may be advanced or withdrawn through launch tube **18**. Moreover, outer covering or coating **372** may also comprise a lubricious material to facilitate the translation of launch tube relative to tubular body **12**. Either or both coatings **370**, **372** may also ensure the structural integrity of launch tube **18** as well.

30 [0186] In advancing launch tube **18** into a configuration where its distal opening is transverse to the tissue to be pierced, launch tube **18** is preferably advanced until the deployed needle body **380** of the needle assembly emerges from launch tube **18**

perpendicularly to the tissue drawn between the extension members, and particularly to upper extension member 20. Thus, the distal opening of launch tube 18 may be configured to form an angle, β , relative generally to the tissue manipulation assembly, as shown in Fig. 25.

Angle, β , is preferably close to 90° but it may range widely depending upon the amount of 5 tissue grasped as well as the angle desired; thus, the launch tube 18 may be configured to translate over a specified distance via detents or locks to ensure the formed angle.

[0187] Aside from ensuring the deployment angle, β , of launch tube 18, a distal portion of launch tube 18 may be modified to include an extended portion 382 which is configured to remain straight even when launch tube 18 is flexed into its deployment configuration, as 10 shown in Fig. 26A. Extended portion 382 may comprises an uncut portion of launch tube 18 or it may alternatively comprise a strengthened region of the launch tube 18. In either case, the extended portion 382 may provide additional columnar support to needle body 380 during needle deployment from launch tube 18 to help ensure the linear deployment of the needle body 380 into or through the tissue.

15 [0188] Another variation for needle deployment from launch tube 18 may be seen in the cross-sectional views of Figs. 26B and 26C, which show the needle body 380 positioned within the distal portion 382 of launch tube 18. To ensure deployment of needle body 380 in a perpendicular or desired trajectory, needle body 380 may define a cross-sectional shape, other than circular, which is keyed to the extended distal portion 382 of launch tube 18.

20 Thus, needle body 380 may define an elliptical cross-sectional shape within a complementary elliptically-shaped distal portion 384, as seen in Fig. 26B. Alternatively, needle body 380 may be configured into a polygonal shape, e.g., octagonal, within an octagonally-shaped distal portion 386, as seen in Fig. 26C. Any number of other cross-sectional shapes may be employed, e.g., rectangles, hexagons, heptagons, octagons, etc.

25 [0189] Rather than utilizing various cross-sectional shapes, needle body 390 may instead be keyed to launch tube 394 to ensure a specified deployment trajectory of needle body 390 from keyed launch tube 394, as shown in the cross-sectional view of Fig. 27A. One variation for keying may include attaching or forming a key or projection 392, e.g., a length of wire, along one or more sides of needle body 390, as shown in the side view of needle body 390 30 and delivery catheter 398. Launch tube 394 may define a groove or channel 396 along an inner surface through which the key 392 on needle body 390 may travel within while maintaining an orientation of needle body 390 relative to launch tube 394.

[0190] Yet another variation for ensuring needle trajectory from the launch tube may be seen in the partial cross-sectional view of Fig. 28. Various features of the tissue manipulation assembly have been omitted merely for clarity. As shown, launch tube 400 may be overdriven relative to the tissue manipulation assembly and upper extension member 20, i.e., 5 the angle, θ , formed between the deployed needle body 402 and upper extension member 20 is greater than 90° . The launch tube 400 and deployed needle body 402 may be overdriven to ensure that the trajectory of needle body 402 is directed towards the assembly rather than away from the assembly.

[0191] Any of the launch tube variations described herein is not intended to be limited to 10 the examples described but is intended to be utilized in any number of combinations with other aspects of other variations as practicable. Moreover, any of the variations relating to the launch tube variations may also be used in any number of combinations, as practicable, with variations of other features as described above, if so desired.

[0192] NEEDLE BODY

[0193] Generally, the launch tube needle is preferably a hollow tapered needle body which 15 is configured to pierce into and through tissue. The needle body may have a variety of tapered piercing ends to facilitate its entry into tissue. One variation which may be utilized to ensure the needle trajectory through the tissue may be seen in Fig. 29A, which shows curved or curvable needle body 410 deployed from launch tube 18.

[0194] In this variation, needle body 410 may be constrained into a straightened 20 configuration when positioned within launch tube 18. However, once deployed from launch tube 18, needle body 410 may be adapted to reconfigure itself into a curved configuration directed towards the tissue manipulation assembly. Thus, curved needle body 410 may be made from a super elastic alloy or shape memory alloy such as Nitinol. Fig. 29B shows 25 another variation in which curved needle body 410 may be launched from an under-deployed launch tube 412.

[0195] Another variation for curving the needle body is illustrated in the side view of Fig. 30. In this variation, needle body 420 may be curved via an anvil 422 configured to receive 30 and deflect the travel of needle body 420 into a curved needle body. Needle body 420 may be comprised of a super elastic alloy such as Nitinol. Anvil 422 may be mounted on either lower extension member 26, as shown in the figure, or upper extension member 20, depending upon the desired results.

[0196] Yet another variation of the needle body may be seen in the illustrative side view of Fig. 31 where the needle body may be replaced with a fiber optic needle **430**. Such a needle **430** may be deployed through the launch tube **18** to provide visualization of the tissue region prior to, during, or after anchor deployment. Alternatively, fiber optic needle **430** may be advanced directly into or through the tissue region for visualization of the tissue. As shown, fiber optic needle **430** may be in communication via fiber optic wire or wires **432** to a processor **434** and an optional monitor **436** for viewing the tissue region from outside the patient's body.

[0197] In another alternative, advancement of the needle body into and/or through the tissue may be facilitated via an ultrasonic vibrating needle body **440**, as shown in Fig. 32. Vibrating needle body **440** may be electrically connected via wires **442** to power source **444** for driving the needle body, e.g., using a piezoelectric transducer to supply the vibratory motion.

[0198] Fig. 33 illustrates yet another alternative where rather than utilizing a vibrating needle body, a torqueable needle body **450**, which may be torqued about its proximal end, may be utilized to facilitate entry into the tissue. The torqueable needle body **450** may be connected via a catheter length having high-torque characteristics, e.g., via braiding along the catheter shaft. Moreover, needle body **450** may further define threading **452** over its outer surface to facilitate entry of the needle body **450** into the tissue. To remove the needle body **450** from the tissue, the direction of torque may simply be reversed while pulling proximally on needle body **450**.

[0199] Rather than deploying anchors from the needle assembly via a distal opening in the needle body, the tissue anchor may alternatively be deployed through one or more side openings defined proximally of the distal tip of the needle body. As seen in the detail view of alternative needle body **460** in Fig. 34A, tissue anchor **60** may be deployed from needle body **460** through side opening **462**. A ramp or taper **464** may be defined within needle body **460** leading to side opening **462** to facilitate the ejection of the tissue anchors from needle body **460**. Fig. 34B shows another alternative needle body **466** having a side opening **462**. This variation, however, includes a tapered needle body with needle knife **468** projecting distally from needle body **466**. Needle knife **468** may be utilized to facilitate the initial entry into the tissue while tapered needle body **466** may be used to dilate the opening created by needle knife **468** and facilitate the entry of needle body **466** into and/or through the tissue.

[0200] Another variation on the needle body and launch tube is shown in Figs. 35A to 36C. Fig. 35A shows an end view looking directly along tubular body 12 towards the tissue manipulation assembly with the launch tube 470 flexed into its deployment configuration. Figs. 35B and 35C show the end view of Fig. 35A where the assembly is angled relatively to 5 the left and to the right, respectively. The terms “left” and “right” are intended to refer only to the orientation of the assembly as shown in the figures and are used for illustrative purposes. Fig. 36A shows a top view of the assembly corresponding to Fig. 35A while Figs. 36B and 36C also show top views corresponding to Figs. 35B and 35C, respectively. When the tissue assembly is visualized within the patient’s body via a laparoscope or endoscope, 10 determining the orientation of the assembly with respect to the tissue may at times be difficult typically due to the lack of depth perception. Thus, to aid with orientation of the assembly when oriented at some angle, ω , as shown in Figs. 35B, 35C, 36B and 36C, portions of the assembly, such as launch tube 470 or the needle assembly, may be coated or covered with a color, e.g., red, orange, yellow, green, blue, indigo, violet, silver, black, or combinations 15 thereof. The aid of coloring portions of the assembly may help with gaining orientation of the device.

[0201] Aside from coloring the tissue manipulation assembly, portions of the needle assembly may also be colored as well. Fig. 37A shows a needle body 480 which may be colored with any of the colors described above to facilitate orientation of the needle body 480 20 when deployed from the launch tube. In another alternative, needle body 482 may have gradations or indicators 484 along its surface, as shown in Fig. 37B, to provide a visual indication to the surgeon or physician of the position of needle body 482 when advanced into or through the tissue or when deployed from the launch tube. Each of the gradations 484 may be separated by a uniform distance or various positions along the needle body 482 may be 25 marked to indicate specified locations.

[0202] Fig. 37C shows yet another variation in which the outer surface of needle body 486 may be dimpled 488. The presence of dimples 488 may be used to enhance the visualization of needle body 486 within the patient body. Moreover, dimples 488 may also enhance the visualization of needle body 486 under ultrasound imaging, if utilized, either for imaging the 30 position of needle body 486 or for locating needle body 486 within the patient’s body if the needle body 486 were to inadvertently break off.

[0203] Yet another variation is shown in the cross-sectional view of needle body **490** in Fig. 37D. The outer surface of needle body **490** may be coated or covered with a radio-opaque material **492** to further enhance visualization of the needle body **490**, for example, if x-ray or fluoroscopic imaging were utilized. The radio-opaque coating **492**, e.g., platinum, nickel, etc., may also be further coated with a lubricious material to facilitate needle insertion into and/or through the tissue.

[0204] Any of the needle body and needle assembly variations described herein is not intended to be limited to the examples described but is intended to be utilized in any number of combinations with other aspects of other variations as practicable. Moreover, any of the variations relating to the needle body variations may also be used in any number of combinations, as practicable, with variations of other features as described above, if so desired.

[0205] HANDLE ASSEMBLY

[0206] The tissue manipulation assembly may be manipulated and articulated through various mechanisms. One such assembly which integrates each of the functions into a singular unit may be seen in the handle assembly which is connected via tubular body **12** to the tissue manipulation assembly. Such a handle assembly may be configured to separate from tubular body **12**, thus allowing for reusability of the handle. Moreover, such a handle may be fabricated from a variety of materials such as metals or plastics, provided that the materials are preferably biocompatible. Examples of suitable materials may include stainless steel, PTFE, Delrin®, etc.

[0207] One variation of a handle assembly is shown in the illustrative side view of handle **500** in Fig. 38A with half of handle enclosure **502** removed for clarity for discussion purposes. As shown, handle enclosure **502** may connect with tubular body **12** at its distal end at tubular interface **504**. The proximal end of handle **500** may define acquisition member opening **506** which opens to acquisition member receiving channel **508** defined through enclosure **502** from opening **506** to tubular interface **504**. The acquisition member **28** may be routed through receiving channel **508** with the proximal end **510** of acquisition member **28** extending proximally of enclosure **502** for manipulation by the user. Acquisition member proximal end **510** may further have an acquisition member rotational control **512** that the user may grasp to manipulate acquisition member **28**.

[0208] Acquisition member receiving channel **508** preferably has a diameter which is sufficiently large enough to allow for the translational and rotational movement of acquisition member through the receiving channel **508** during tissue manipulation. Acquisition member lock **524**, e.g., a screw or protrusion, may also extend at least partially into acquisition

5 member receiving channel **508** such that lock **524** may be urged selectively against acquisition member **28** to freeze a position of acquisition member **28**, if so desired. The terminal end of receiving channel **508** may extend to tubular interface **504** such that receiving channel **508** and tubular body **12** are in communication to provide for the passage of acquisition member **28** therethrough.

10 [0209] In addition to the acquisition member controls, the handle enclosure **502** may also provide a needle assembly receiving channel **514** through which needle assembly control **516** and needle assembly catheter **518** may be translated through. Needle assembly receiving channel **514** may extend from needle assembly opening **520** also to tubular interface **504**. Needle assembly receiving channel **514** extends to tubular interface **504** such that needle 15 assembly receiving channel **514** and tubular body **12** are also in communication to provide for the passage of needle assembly catheter **518** therethrough.

20 [0210] In operation, once the tissue to be plicated has been acquired and drawn between the lower and upper extension members by acquisition member **28**, as described above, the launch tube **18** may be advanced distally and rotated into its deployment configuration. Once positioned for deployment, the needle assembly may be advanced into and/or through the tissue by urging needle assembly control **516** and needle assembly catheter **518** distally into needle assembly receiving channel **514**, as shown by the advancement of control **516** in Fig. 38B. The tissue anchors may then be deployed from the needle assembly catheter **518** via the needle assembly control **516**, as further described below. Withdrawal of the needle assembly 25 from the tissue may be accomplished by the proximal withdrawal of needle assembly control **516** and assembly catheter **518**.

30 [0211] Tissue manipulation articulation control **522** may also be positioned on handle **500** to provide for selective articulation of the tissue manipulation assembly, as shown above in Figs. 23A to 23C. This variation shows articulation control **522** rotatably positioned on handle enclosure **502** such that articulation control **522** may be rotated relative to handle **500** to selectively control the movement of the tissue manipulation assembly. Articulation control **522** may be operably connected via one or several control wires attached between articulation

control **522** and the tissue manipulation assembly. The control wires may be routed through tubular interface **504** and extend through tubular body **12**.

[0212] Fig. 38C shows another variation of handle enclosure **502** where the tissue manipulation articulation control **526** may be positioned on a side surface of handle enclosure **502**. Articulation control **526** may include a ratcheting mechanism **528** within enclosure **502** to provide for controlled articulation of the tissue manipulation assembly.

[0213] Figs. 39A to 39C show top, side, and cross-sectional views, respectively, of another variation on the handle assembly. As seen in Figs. 39A and 39B, an advancement control **530** may be adapted to selectively slide translationally and rotationally through a defined advancement channel or groove **532** defined within handle enclosure **502**. Advancement control **530** may be used to control the deployment and advancement of needle assembly control **516** as well as deployment of the launch tube, as described in further detail below.

[0214] Fig. 39D shows an assembly side view of the handle assembly, tubular body **12**, and tissue manipulation assembly and the corresponding motion of the assembly when manipulated by the handle. As described above, tissue acquisition member proximal end **510** and acquisition member control **512** may be advanced or withdrawn from the handle enclosure **502** in the direction of arrow **534** to transmit the corresponding translational motion through tubular body **12** to tissue acquisition member **28** and tissue grasper **30**, as indicated by the direction of corresponding arrow **536**. Likewise, when acquisition member control **512** is rotated relative to handle enclosure **502**, as indicated by rotational arrow **538**, the corresponding rotational motion is transmitted through tubular body **12** to tissue grasper **30** for screwing into or unscrewing from tissue, as indicated by corresponding rotational arrow **540**. As mentioned above, tubular body **12** may be rigid or flexible depending upon the application utilized for the device.

[0215] Likewise, longitudinal translation of needle assembly control **516** relative to enclosure **502**, as indicated by the arrow may transmit the corresponding longitudinal motion to the needle assembly through the launch tube when reconfigured for deployment. The tissue manipulation assembly articulation control **522** may also be seen in this handle variation as being rotatable in the direction of arrow **542** relative to handle enclosure **502**.
Depending upon the direction of articulation, control **522** may be manipulated to elicit a corresponding motion from the tissue manipulation assembly about hinge or articulatable section **350** in the direction of arrows **544**.

[0216] Another handle variation may be seen in the perspective view of handle assembly **550**, as shown in Fig. 40A. This particular variation may have handle enclosure **552** formed in a tapered configuration which allows for the assembly **550** to be generally symmetrically-shaped about a longitudinal axis extending from its distal end **554** to its proximal end **556**.

- 5 The symmetric feature of handle assembly **550** may allow for the handle to be easily manipulated by the user regardless of the orientation of the handle enclosure **552** during a tissue manipulation procedure. An additional feature which may further facilitate the ergonomic usability of handle assembly **550** may further include at least one opening **558** defined through the enclosure **552** to allow the user to more easily grip and control the handle
10 **550**. Another feature may include grips **560**, **562** which may extend from either side of enclosure **552**.

[0217] As seen in the figure, acquisition member **564** may include additional features to facilitate control of the tissue. For instance, in this variation, in addition to the rotational control **566**, an additional rotational control **568** may extend proximally from control **566** and
15 have a diameter smaller than that of control **566** for controlling fine rotational motion of acquisition member **564**.

[0218] Fig. 40B shows a side view of the handle assembly **550** of Fig. 40A with the enclosure **552** partially removed for clarity. As shown, needle assembly control **570** may be seen inserted within an additional needle deployment mechanism **576**, as described below in
20 further detail, within needle assembly receiving channel **574**. Acquisition member **564** may also be seen positioned within acquisition member receiving channel **572**.

[0219] Yet another variation of the handle assembly may be seen in the side view of the handle assembly of Fig. 41A where the handle enclosure **522** is partially removed for clarity. In this variation, needle deployment mechanism lock **580**, e.g., a screw or protrusion, may be
25 configured to operably extend at least partially into needle assembly receiving channel **574** to selectively lock the launch tube and/or needle assembly control within receiving channel **574**. Also shown is acquisition member receiving channel **582** through which the acquisition member may be translated and/or rotated. Acquisition member lock **584** may also be seen to extend at least partially into the acquisition member receiving channel **582** to selectively lock
30 the acquisition member position, if so desired. The acquisition member receiving channel **582** may be optionally threaded **586** such that the acquisition member may be advanced or withdrawn using a screw-like mechanism.

[0220] An additional needle deployment mechanism lock 594 may also be seen pivotally mounted about pivot 596 within enclosure 522. Mechanism 594 may be biased via deployment mechanism biasing element 598, e.g., a spring, to maintain a biasing force against mechanism 594 such that the needle assembly control may automatically become 5 locked during advancement within enclosure 522 to allow for a more controlled anchor deployment and needle assembly advancement.

[0221] Moreover, one or more pivotable tissue manipulation assembly controls 588 may be mounted to enclosure 522 and extend from one or both sides of enclosure 522 to provide for articulation control of the tissue manipulation assembly, as described above. As presently 10 shown in Fig. 41B in the detail side view from the handle assembly of Fig. 41A, one or more control wires 592 may be connected to control 588 at control wire attachment points 600. Control 588 may pivot about tissue acquisition pivot 590 located within handle enclosure 522. As control 588 is pivoted, the articulation of control wires 592 may articulate a position 15 of the tissue manipulation assembly, as discussed above. Fig. 41B shows an example of the range of motion which may be possible for control 588 as it is rotated about pivot 590.

[0222] Fig. 42A shows a side view of another variation of handle enclosure 610 which incorporates a needle deployment locking and advancement control 612 which is adapted to be advanced and rotated within needle deployment travel 614 into various positions corresponding to various actions. Locking control 612 may be utilized in this variation to 20 selectively control access of the needle assembly within handle enclosure 610 as well as deployment of the needle assembly and launch tube advancement with a single mechanism. A needle assembly, such as needle assembly 570, may be advanced into handle enclosure 610 with locking control 612 initially moved into needle assembly receiving position 616, shown also in the end view of Fig. 42B. Once the needle assembly has been initially introduced into 25 enclosure 610, the needle assembly may be locked within enclosure 610 by rotating locking control 612 into its needle assembly locking position 618, clockwise rotation as shown in the end view of Fig. 42C. The needle assembly may be locked within enclosure 610 to prevent the accidental withdrawal of the needle assembly from the enclosure 610 or inadvertent advancement of the needle assembly into the tissue.

30 [0223] With locking control 612 in the needle assembly locking position 618, the needle deployment mechanism within enclosure 610 may also be longitudinally translated in a distal direction by urging locking control 612 distally within needle deployment travel 614. Urging

locking control **612** distally translates not only the needle deployment mechanism within enclosure **610**, but may also translate the launch tube distally such that the launch tube distal portion is pivoted into its deployment configuration, as described above. As the needle deployment mechanism is distally translated within enclosure **610**, the needle assembly may 5 also be urged distally with the deployment mechanism such that needle assembly becomes positioned within the launch tube for advancing the needle body into the tissue.

[0224] Once locking control **612** has been advanced distally, locking control **612** may again be rotated into the needle assembly release position **620**, clockwise rotation as shown in the end view of Fig. 42D. Once in the release position **620**, the needle assembly may be free to 10 be translated distally within enclosure **610** for advancing the needle assembly and needle body relative to the launch tube and enclosure **610**. To remove the needle assembly from enclosure **610**, the steps may be reversed by moving locking control **612** proximally back to its initial needle assembly receiving position **616** so that the needle assembly is unlocked from within enclosure **610**. A new needle assembly may then be introduced into enclosure 15 **610** and the process repeated as many times as desired.

[0225] Details of one variation of the locking mechanism disposed within the handle enclosure **610** are shown in the perspective view of Fig. 43A. The other elements of the handle assembly have been omitted from this illustration for clarity. The locking mechanism may generally be comprised of outer sleeve **630** disposed about inner sleeve **632**. Outer 20 sleeve **630** preferably has a diameter which allows for its unhindered rotational and longitudinal movement relative to inner sleeve **632**. Needle deployment locking control **612** may extend radially from outer sleeve **630** and protrude externally from enclosure **610**, as described above, for manipulation by the user. Outer sleeve **630** may also define needle assembly travel path **636** along its length. Travel path **636** may define the path through 25 which needle assembly **570** may traverse in order to be deployed. Needle assembly **570** may define one or more guides **638** protruding from the surface of assembly **570** which may be configured to traverse within travel path **636**. Inner sleeve **634** may also define guides **634** protruding from the surface of inner sleeve **634** for traversal within grooves defined in handle 30 enclosure **610**. Moreover, outer sleeve **630** is preferably disposed rotatably about inner sleeve **632** such that outer sleeve **630** and inner sleeve **632** are configured to selectively interlock with one another in a corresponding manner when locking control **612** is manipulated into specified positions.

[0226] Turning to Figs. 43B to 43E, the operation of the locking mechanism of Fig. 43A is described in further detail. As needle assembly 570 is initially introduced into handle enclosure 610 and the locking mechanism, needle assembly 570 may be rotated until guides 638 are able to slide into longitudinal receiving channel 640 of travel path 636 defined in outer sleeve 630, as shown in Figs. 43B and 43C. Locking control 612 may be partially rotated, as described above in Figs. 42B and 42C, such that outer sleeve is rotated with respect to needle assembly 570 and guides 638 slide through transverse loading channel 642, as shown in Fig. 43D. In this position, the locking mechanism may be advanced distally to deploy the launch tube and to also advance needle assembly 570 distally in preparation for needle assembly 570 deployment. Once the launch tube has been desirably advanced, locking control 612 may again be partially rotated, as shown in Fig. 42D, such that guides 638 on needle assembly 570 are free to then be advanced within longitudinal needle assembly channel 644 relative to the handle enclosure 610 for deploying the needle assembly 570 from the launch tube and into or through the tissue. As mentioned above, the needle assembly 570 may be removed from enclosure 610 and the locking mechanism by reversing the above procedure.

[0227] As above, any of the handle assembly variations described herein is not intended to be limited to the examples described but is intended to be utilized in any number of combinations with other aspects of other variations as practicable. Moreover, any of the variations relating to the handle assembly variations may also be used in any number of combinations, as practicable, with variations of other features as described above, if so desired.

[0228] NEEDLE DEPLOYMENT ASSEMBLY

[0229] As described above, needle deployment assembly 650 may be deployed through approximation assembly 10 by introducing needle deployment assembly 650 into the handle 16 and through tubular body 12, as shown in the assembly view of Fig. 44, such that the needle assembly 656 is advanced from the launch tube and into or through approximated tissue. Once the needle assembly 656 has been advanced through the tissue, the anchor assembly 658 may be deployed or ejected. Anchor assembly 658 is normally positioned within the distal portion of tubular sheath 654 which extends from needle assembly control or housing 652. Once the anchor assembly 658 has been fully deployed from sheath 654, the spent needle deployment assembly 650 may be removed from approximation assembly 10, as

described above, and another needle deployment assembly may be introduced without having to remove assembly 10 from the patient. The length of sheath 654 is such that it may be passed entirely through the length of tubular body 12 to enable the deployment of needle assembly 656 into and/or through the tissue.

5 [0230] Fig. 45A shows a detailed assembly view of the needle deployment assembly 650 from Fig. 44. In this variation, elongate and flexible sheath or catheter 654 may extend removably from needle assembly control or housing 652. Sheath or catheter 654 and housing 652 may be interconnected via interlock 660 which may be adapted to allow for the 10 securement as well as the rapid release of sheath 654 from housing 652 through any number of fastening methods, e.g., threaded connection, press-fit, releasable pin, etc. Needle body 662, which may be configured into any one of the variations described above, may extend from the distal end of sheath 654 while maintaining communication between the lumen of sheath 654 and needle opening 664.

15 [0231] Elongate pusher 666 may comprise a flexible wire or hypotube which is translationally disposed within sheath 654 and movably connected within housing 652. A proximally-located actuation member 668 may be rotatably or otherwise connected to housing 652 to selectively actuate the translational movement of elongate pusher 666 relative to sheath 654 for deploying the anchors from needle opening 664. Anchor assembly 658 may be seen positioned distally of elongate pusher 666 within sheath 654 for deployment from 20 sheath 654. Needle assembly guides 670 may also be seen protruding from housing 652 for guidance through the locking mechanism described above. Fig. 45B shows an exploded assembly view of the needle deployment assembly 650 from Fig. 45A. As seen, sheath 654 may be disconnected from housing 652 via interlock 660 to reveal the elongate pusher 666 connected to housing 652 and the distal and proximal anchors 58, 60, respectively, of anchor 25 assembly 658.

[0232] Figs. 46A and 46B show partial cross-sectional views of one variation of housing 652. As shown in fig. 46A, elongate pusher 666 may be attached to shuttle 682, which in turn may be connected to threaded interface element 686. As actuation member 668 is manipulated, e.g., by rotating it clockwise, lead screw 684 may be rotated about its 30 longitudinal axis to advance threaded interface element 686 over lead screw 684 distally through shuttle channel 680, as shown in Fig. 46B, where shuttle 682 has been advanced entirely through shuttle channel 680. Tubular sheath interlock 688 may be seen at the distal

portion of housing 652 through which the elongate pusher 666 may be advanced. To reverse the direction of elongate pusher 666 and shuttle 682, actuation member 668 may be reversed in the opposite direction.

[0233] Another variation of the needle deployment assembly may be seen in Figs. 47A and

5 47B which show assembly side views. In this variation, housing 652 may define an indicator window 690 along the length of housing 652 to enable viewing of a visual indicator 692 which may be utilized to indicate the position of the elongate pusher 666 within the sheath 654. In the illustration of Fig. 47A, as actuation member 668 is manipulated to advance pusher 666 distally, indicator 692 may move correspondingly within window 690. Positional 10 indicators may also be marked along window 690 to indicate to the user when specified limits have been reached. For instance, positional indicator 694 may be marked such that alignment of indicator 692 with positional indicator 694 is indicative to the user that distal anchor 58 has been deployed from sheath 654.

[0234] Likewise, an additional positional indicator 696 may be marked such that alignment

15 of indicator 692 with positional indicator 694 is indicative to the user that the proximal anchor 60 has also been deployed from sheath 654, as shown in Fig. 47B. Any number of positional indicators or methods for visually marking may be utilized as the above examples are merely intended to be illustrative and not limiting. Moreover, to further facilitate the visualization of anchor positioning within sheath 654, the sheath itself may be fabricated 20 from a transparent material, such as plastics, so that the user may visually locate a position of one or both anchors during anchor deployment into or through the tissue.

[0235] Fig. 47C shows an illustrative cross-sectional view of the launch tube 18 in its deployment configuration. Tubular sheath 654 and needle body 662 may be seen positioned within the distal portion of launch tube 18 ready for deployment into any tissue (not shown 25 for clarity) which may be positioned between upper and lower extension members 20, 26. Also shown are distal and proximal anchors 58, 60, respectively (suture is not shown for clarity), positioned within sheath 654 distally of elongate pusher 666.

[0236] Fig. 48 shows an assembly view of yet another variation in which manipulatable

needle assembly 700 may be utilized with approximation assembly 10. Similar to the

30 assembly above, manipulatable needle assembly 700 may be deployed through approximation assembly 10 by introducing needle assembly 700 into the handle 16 and through tubular body 12. Once the needle assembly has been advanced through the tissue, an

anchor assembly may be deployed or ejected and/or the tissue or suture may be manipulated via the assembly 700. A further detailed description of manipulatable needle assembly 700 is disclosed in co-pending U.S. Pat. App. Serial No. 10/898,684, filed July 23, 2004 and entitled "Manipulatable Grasping Needle" (Attorney Docket No. 021496-003000US), which is 5 incorporated herein by reference in its entirety.

[0237] As shown in Fig. 48, an elongate flexible member 702 may be tubular such that at least one lumen is defined through the length of flexible member 702. Handle 704 may be positioned at a proximal end of flexible member 702 and control handle 706 may be likewise positioned. Control handle 706 may be configured to enable the articulation of piercing and 10 grasping assembly 708 into an open or closed configuration, as described in further detail below. Control handle 708, as well as handle 704, which is positioned at a distal end of flexible member 702, may be operably connected to piercing and grasping assembly 708, e.g., via control wires, which may run through the length of flexible member 702.

[0238] Flexible member 702 may be made from a variety of flexible materials such as 15 polymers. If made from a polymeric material, flexible member 702 may be reinforced along its length as necessary using various methods such as interspersing metallic braids, weaves, reinforcing wires, etc., throughout the length of the flexible member 702. Alternatively, metallic materials, e.g., stainless steel, platinum, etc., and particularly superelastic metals and alloys, e.g., Nitinol, etc., may be utilized in constructing flexible member 702 provided that 20 the material is sufficiently adapted to flex when manipulated. In the case of stainless steel or like metals, the length of flexible member 702 may be scored or perforated to allow for additional flexibility. Moreover, the diameter of flexible member 702 may be varied to suit the application in which assembly 700 may be employed. For example, if assembly 700 were advanced, e.g., through a conventional endoscope for use in a patient's stomach, flexible 25 member may range anywhere in diameter from 2-3 mm and may have a length greater than or less than 100 cm. These dimensions are merely intended to be illustrative and are not intended to limit the size or scope of the assembly 700.

[0239] As generally shown, piercing and grasping assembly 708 may be comprised of 30 needle body 710, which has a tapered or sharpened tip 712 for piercing into or through tissue. Needle body 710 may also define an opening or lumen 714 therethrough for retaining and passing a tissue anchor, as described further below. As seen in the detail side view of Fig. 49A, piercing and grasping assembly 708 may be configured into a low-profile closed

configuration for advancement into the body and for piercing into or through tissue. As piercing and grasping assembly 708 is advanced into or through tissue, a length of suture 720 may be releasably retained by assembly 708 between needle body 710 and grasping arm 716, which may be positioned proximally of tip 712 and/or needle body 710.

5 [0240] Once piercing and grasping assembly 708 has been desirably advanced into or through tissue, assembly 708 may be actuated into an open configuration where grasping arm 716 may project from needle body 710, as shown in Fig. 49B. In the open configuration, grasping arm 716 may be open relative to needle body 710 such that suture 720 may be released from piercing and grasping assembly 708. Alternatively, piercing and grasping 10 assembly 708 may be manipulated to grasp a free length of suture. Linkage assembly 718, which may be actuated via a push and/or pull wire (not shown) contained within tubular member 702, may be used to open and close needle body 710 and grasping arm 716. As shown, both needle body 710 and grasping arm 716 may each be actuated into an opened configuration relative to tubular member 702; alternatively, linkage assembly 718 may be 15 utilized to actuate a single member, i.e., needle body 710 or grasping arm 716, into an opened configuration for suture manipulation or release.

[0241] Elongate tubular member 702 may be flexible or it may also be constructed as a rigid shaft. In either case, one or several portions of elongate member 702 may comprise an articulatable section 30 along a length of elongate member 702. A section of member 702 20 just proximal of piercing and grasping assembly 708 may be configured to be articulatable such that assembly 708 may be articulated via handle 704. One or several control wires may be routed through elongate member 702 in any number of ways to enable articulatable section 30 to conform to a desired shape. An elongate member 702 having one or several 25 articulatable sections 30 may enable assembly 708 to be manipulated about or around tissue such that suture manipulation is facilitated.

[0242] The piercing and grasping assembly 708 may be utilized in a variety of different procedures. In one instance, assembly 708 may be advanced into a hollow body organ, e.g., a stomach, and used to pierce through created tissue plications and deposit soft tissue anchors for securing the tissue plications. Examples of methods and devices for creating tissue plications may be seen in further detail in U.S. Pat. App. Serial No. 10/735,030 which has 30 been incorporated by reference above. As shown in Fig. 50A, an expandable tissue anchor 722 may be seen positioned within opening 714 of needle body 710 for delivery. Suture 720

ending in terminal loop 724 may be seen passing through and from tissue anchor 722. Once assembly 708 has been desirably passed through tissue and appropriately positioned, tissue anchor 722 may be ejected from needle body 710, e.g., using a pusher mechanism. Once free from the constraints of needle body 710, tissue anchor 722 may be free to expand for 5 anchoring against a tissue surface, as seen in Fig. 50B. Further details relating to tissue anchors and mechanisms which may be utilized for ejecting and positioning such anchors are disclosed in further detail in U.S. Pat. App. Serial No. 10/840,950 filed May 7, 2004, which has been incorporated herein by reference above in its entirety.

[0243] As above, any of the needle assembly variations described herein is not intended to 10 be limited to the examples described but is intended to be utilized in any number of combinations with other aspects of other variations as practicable. Moreover, any of the variations relating to the needle assembly variations may also be used in any number of combinations, as practicable, with variations of other features as described above, if so desired.

15 [0244] **ANCHOR DEPLOYMENT**

[0245] In deploying the anchors into or through the tissue, one or more anchors may be positioned within the launch tube for deployment. As described above, deployment of the anchors may be accomplished in one method by pushing the anchors via the elongate pusher element until the anchor is ejected from the needle body opening. Once the anchor is free 20 from the constraints of the needle catheter, it may reconfigure into an expanded configuration for placement against the tissue surface.

[0246] To ensure that the anchor is not prematurely ejected from the needle assembly, various interlocking features or spacing elements may be employed. As shown in the partial cross-sectional view of Fig. 51A, the collar of proximal anchor 60 and the distal end of 25 elongate pusher may be interlocked with one another via a temporary interlocking feature 730. Likewise, the adjacent collars of distal and proximal anchors 58, 60, respectively, may be optionally interlocked with one another via a temporary interlocking feature 732 as well. Such an interlocking feature may enable the anchor assembly to be advanced distally as well as withdrawn proximally through sheath 654 and needle body 662 in a controlled manner 30 without the risk of inadvertently pushing one or more anchors out of needle body 662.

[0247] Aside from the use of interlocking features, one or more spacing elements 734 may also be placed between adjacent anchors within sheath 654 in another variation as shown in

Fig. 51C. In use, as distal anchor 58 is initially deployed, spacer 734 may provide additional distance between the adjacent anchors so that proximal anchor 60 is not inadvertently deployed along with distal anchor 58. Spacer element 734 may optionally include interlocking features to temporarily interlock with the adjacent anchors. Moreover, when 5 proximal anchor 60 is deployed, spacer element 734 may be ejected into the patient's body, e.g., the stomach, to simply degrade or pass naturally from the patient. Accordingly, such a spacer 734 is preferably made from any number of biocompatible and/or biodegradable materials.

[0248] Aside from the interlocking anchor features, the suture 76 which may be routed 10 through anchors 58, 60 to interconnect them may also be varied in placement with respect to the anchors. As shown in Fig. 51A, suture 76 may be optionally routed such that its terminal end is deployed initially with distal anchor 58. Alternatively, suture 76 may be routed such that its terminal end is deployed lastly along with proximal anchor 60. Other variations for routing the suture 76 may be employed as practicable as the foregoing examples are 15 described merely as examples and are not intended to be limiting in their description.

[0249] Turning back to the anchor interlocking features, Figs. 52A and 52B show perspective views of distal anchor 58 and proximal anchor 60, respectively, having one variation for temporarily interlocking the anchors. The anchors 58, 60 are shown in their unexpanded delivery configuration when positioned within the tubular delivery sheath or 20 catheter 654. As shown, the proximal collar of distal anchor 58 may have a circumferential-tab locking feature 744, as shown in Fig. 52A, which is configured to inter-fit in a complementary manner with circumferential-tab locking feature 742 on proximal anchor 60, as shown in Fig. 52B. Likewise, the proximal collar of proximal anchor 60 may also have a circumferential-tab locking feature 740 which is configured to inter-fit also in a 25 complementary manner with the locking feature 746 located on the distal end of elongate pusher 666, as shown in the detail perspective view of Fig. 52C.

[0250] Figs. 53A and 53B show another variation on the interlocking feature where the anchor may have a longitudinal-tab locking feature 750 or a receiving-tab locking feature 752 which is configured to inter-fit with one another in a complementary manner. Fig. 53B 30 shows the distal end of an elongate pusher variation having a longitudinal-tab locking feature 754 for inter-fitting with the proximal collar of an adjacent anchor.

[0251] With any of the interlocking features described herein, they are preferably configured to temporarily lock adjacent anchors and/or the anchor to the elongate pusher to one another. The positioning and orientation of the adjacent anchors and elongate pusher may be such that the abutting ends of each are configured to remain interlocked with one another when constrained by the inner surface of the sheath 654. However, when an anchor is ejected from the constraints of the sheath 654 and the alignment of the anchors is skewed, the interlocking feature is preferably adapted to thus unlock itself and thereby release the ejected anchor.

[0252] Fig. 54A shows another variation on a curved-tab interlocking feature 760. Fig. 10 54B shows distal and proximal anchors 58, 60, respectively, interlocked via the curved-tab feature 760 when constrained in the sheath 654. Fig. 54C shows distal anchor 58 having been ejected and released from the interlocking feature 760. The interlocking feature is not shown on the proximal end of proximal anchor 60 and other features such as the elongate pusher and suture have been omitted merely for the sake of clarity.

[0253] Figs. 55A, 55B, and 55C likewise show angled interlocking feature 770 in a detail view, between adjacent anchors, and with distal anchor 58 being released from the interlocking feature 770, respectively.

[0254] Figs. 56A, 56B, and 56C likewise show interlocking feature 780 having a tab 782 and a complementary receiving groove 784 in a detail view, between adjacent anchors, and with distal anchor 58 being released from the interlocking feature 780, respectively.

[0255] Figs. 57A, 57B, and 57C likewise show interlocking feature 790 having a pin 792 and a complementary receiving groove 794 in a detail view, between adjacent anchors, and with distal anchor 58 being released from the interlocking feature 790, respectively.

[0256] Figs. 58A, 58B, and 58C likewise show rotational interlocking feature 800 having a helix or coil 802 and a complementary inter-fitting pin 804 in a detail view, between adjacent anchors, and with distal anchor 58 being released from the interlocking feature 800, respectively.

[0257] Figs. 59A, 59B, and 59C likewise show electrolytic interlocking feature 810 having an inter-joined electrolytically-erodable joint 812 in a detail view, between adjacent anchors, and with distal anchor 58 being released from the interlocking feature 780, respectively. The electrolytically-erodable joint 812 may be electrically connected via wires (not shown) routed

through sheath 654 to a power source located outside the patient. For release of the anchor, the electrolytically-erodable joint 812 may be eroded and leave eroded joint ends 814, 816 on adjacent anchors.

[0258] Figs. 60A, 60B, and 60C likewise show interlocking feature 820 having a balled joint 822 and a complementary receiving groove 824 in a detail view, between adjacent anchors, and with distal anchor 58 being released from the interlocking feature 820, respectively.

[0259] Figs. 61A, 61B, and 61C likewise show balled interlocking feature 830 in a detail view, between adjacent anchors, and with distal anchor 58 being released from the interlocking feature 830, respectively. Each of the respective ball joints 832, 834 are configured to inter-fit with complementary receiving grooves 836, 838 on adjacent anchors.

[0260] Figs. 62A, 62B, and 62C likewise show magnetic locking feature 840 having respective anchors ends 842, 844 with opposing polarities in a detail view, between adjacent anchors, and with distal anchor 58 being released from the magnetic locking feature 840, respectively. Each of the magnets 842, 844 may be comprised of ferromagnetic materials, or they may be electromagnetically charged.

[0261] Fig. 63 shows yet another variation which may be utilized particularly between an anchor and the elongate pusher. The interlocking feature 850 may comprise a curved or arcuate feature, e.g., circumferential-tab locking feature 744, which may receive a cross-member 854 extending perpendicularly from elongate member 852.

[0262] Fig. 64A shows yet another variation where elongate pusher 666 may have one or several biased retaining arms 860, 862 extending from the distal end of pusher 666. Retaining arms 860, 862 may be biased to extend radially but may be constrained to extend radially inward when positioned within sheath 654. The distal ends of arms 860, 862 may protrude inwardly between the struts of the anchor 60 for manipulation and deployment. When pusher 666 is advanced distally, arms 860, 862 may spring radially open to thereby release anchor 60. The proximal portions of arms 860, 862 may be tapered such that when pusher 666 is withdrawn proximally into sheath 654, the taper on each of the arms 860, 862 allows them to be drawn back into sheath 654.

[0263] Fig. 64B shows another variation in which extension member 864 may extend distally from elongate pusher 666 to form at least one retaining arm 866 which may extend

between one or more adjacent anchors **58, 60**. As pusher **666** is advanced distally, proximal anchor **60** may be released when retaining arm **866** is fully advanced outside of sheath **654** and needle body **662**.

[0264] Fig. 64C shows yet another variation where the proximal anchor **60** may be retained to pusher **666** via a looped member **868** extending from the distal end of pusher **666**. Loop member **868** may simply be looped about the proximal end of proximal anchor **60** and released by simply advancing anchor **60** out of sheath **654**.

[0265] In utilizing any of the interlocking features described herein, needle assemblies may be utilized having multiple anchors for deployment into or through tissue. Fig. 65 shows a partial cross-sectional view of multi-anchor variation **870** in which multiple anchors **872** may be aligned adjacently to one another in series within the sheath **654**. Each of the anchors **872** may be temporarily interlocked with one another such that each anchor **872** may be deployed sequentially in a controlled manner.

[0266] Figs. 66A and 66B show partial cross-sectional side and bottom views of yet another multi-anchor variation **880**. In this variation, sheath **882** may comprise a multi-tabbed assembly having multiple retaining tabs **884** extending partially into the sheath lumen. Each of the tabs **884** may be spaced uniformly relative to one another such that a single anchor **872** may be retained by a single tab **884**, as shown in the Fig. 66A. As pusher **666** advances distally, each of the anchors, with or without interlocking features between adjacent anchors, may be advanced past a tab **884** until the desired number of anchors **872** has been deployed. Each tab **884** is preferably configured to extend only partially into the lumen, as mentioned and as shown in the cross-sectional view of Fig. 66C, and is preferably configured to flex and thereby allow for passage of an anchor **872**.

[0267] Although a number of illustrative variations are described above, it will be apparent to those skilled in the art that various changes and modifications may be made thereto without departing from the scope of the invention. Moreover, although specific configurations and applications may be shown, it is intended that the various features may be utilized in various types of procedures in various combinations as practicable. It is intended in the appended claims to cover all such changes and modifications that fall within the true spirit and scope of the invention.

WHAT IS CLAIMED IS:

- 1 1. A needle assembly for use in forming a tissue fold, comprising:
2 a housing having a shuttle member enclosed within;
3 an elongate pusher adapted to be in communication with the shuttle member
4 and extending from a distal end of the housing;
5 a tubular sheath adapted to receive the elongate pusher therethrough and
6 having a proximal end which is attachable to the housing; and
7 an actuation member disposed on the housing, wherein articulation of the
8 actuation member translates the elongate pusher longitudinally relative to the housing.
- 1 2. The assembly of claim 1 wherein the housing comprises a
2 cylindrically-shaped member.
- 1 3. The assembly of claim 1 wherein the housing defines at least one
2 projection extending therefrom for retaining the needle assembly within a handle.
- 1 4. The assembly of claim 1 wherein the housing comprises an indicator
2 which is indicative of a position of the shuttle member within the housing.
- 1 5. The assembly of claim 4 wherein the indicator comprises a translatable
2 visual marker which is visible through a window defined along a length of the housing.
- 1 6. The assembly of claim 4 further comprising one or more gradations
2 along a length of the housing.
- 1 7. The assembly of claim 1 wherein the elongate pusher is connected to
2 the shuttle member.
- 1 8. The assembly of claim 1 wherein the elongate pusher is flexible.
- 1 9. The assembly of claim 1 wherein the shuttle member comprises a
2 threaded member adapted to be linearly translated over a rotatable threaded shaft.
- 1 10. The assembly of claim 1 further comprising a lubricious lining or
2 coating along an inner surface of the tubular sheath.

1 11. The assembly of claim 1 wherein the tubular sheath comprises a
2 translucent material.

1 12. The assembly of claim 1 wherein the proximal end of the tubular
2 sheath is adapted to be releasably attached to a distal end of the housing.

1 13. The assembly of claim 1 wherein a distal end of the tubular sheath is
2 tapered.

1 14. The assembly of claim 1 further comprising a needle body disposed on
2 a distal end of the sheath.

1 15. The assembly of claim 1 wherein the actuation member is rotatably
2 disposed on a proximal end of the housing.

1 16. The assembly of claim 1 further comprising at least one anchor
2 positionable within the tubular sheath distally of the elongate pusher.

1 17. The assembly of claim 16 wherein the at least one anchor has a low-
2 profile delivery configuration when positioned within the tubular sheath and an expanded
3 configuration when deployed from the tubular sheath.

1 18. The assembly of claim 16 further comprising a second anchor
2 positionable within the tubular sheath adjacent distally to the at least one anchor.

1 19. The assembly of claim 17 further comprising a length of suture
2 between each of the anchors.

1 20. The assembly of claim 19 further comprising a locking mechanism
2 adapted to slide uni-directionally over the suture in a direction towards the anchor.

1 21. A method of deploying one or more anchors in securing a tissue fold,
2 comprising:
3 advancing a needle body disposed on a distal end of a tubular sheath into or through a
4 fold of tissue;

5 manipulating an actuation member disposed on a housing connected to a proximal end
6 of the tubular sheath such that a shuttle member enclosed within the housing urges an
7 elongate pusher through the tubular sheath; and
8 deploying at least one anchor from the tubular sheath via the elongate pusher.

1 22. The method of claim 21 wherein advancing a needle body comprises
2 piercing the needle body and tubular sheath into or through the fold of tissue.

1 23. The method of claim 21 wherein manipulating an actuation member
2 comprises urging the shuttle member distally through the housing.

1 24. The method of claim 21 wherein deploying at least one anchor
2 comprises urging the at least one anchor distally via the elongate pusher until the anchor
3 assumes an expanded configuration.

1 25. The method of claim 21 further comprising advancing the needle body
2 and tubular sheath through an endoscopic device towards the fold of tissue prior to
3 manipulating an actuation member.

1 26. The method of claim 21 further comprising monitoring a position of
2 the shuttle member within the housing via an indicator defined along the housing while
3 manipulating an actuation member.

1 27. The method of claim 21 further comprising deploying a second anchor
2 from the tubular sheath via the elongate pusher.

1 28. The method of claim 21 further comprising removing the needle body
2 and tubular sheath from the fold of tissue.

1 29. The method of claim 28 further comprising advancing a second needle
2 body disposed on a distal end of a second tubular sheath into or through the fold of tissue.

1 30. A tissue anchor for controlled delivery through a lumen, comprising:
2 an anchor body adapted for placement into or against a region of tissue; and
3 a first locking feature located on at least one end of the anchor body which is
4 adapted to interlock with a corresponding second locking feature when positioned within the
5 lumen.

1 31. The tissue anchor of claim 30 wherein the anchor body has a first low-
2 profile configuration when positioned within the lumen and a second expanded configuration
3 when deployed from the lumen for placement into or against the region of tissue.

1 32. The tissue anchor of claim 30 wherein the anchor body is comprised of
2 a shape memory alloy.

1 33. The tissue anchor of claim 33 wherein the anchor body is comprised of
2 Nitinol.

1 34. The tissue anchor of claim 30 wherein the anchor body comprises a
2 plurality of struts extending between a distal collar and a proximal collar.

1 35. The tissue anchor of claim 30 wherein the first locking feature is
2 located on a proximal collar of the anchor body.

1 36. The tissue anchor of claim 36 wherein an additional locking feature is
2 further located on a distal collar of the anchor body.

1 37. The tissue anchor of claim 36 wherein the corresponding second
2 locking feature is located on a distal collar of a second anchor body collinearly adjacent
3 proximal to the anchor body.

1 38. The tissue anchor of claim 38 wherein the second anchor body further
2 comprises a third locking feature located on a proximal collar of the second anchor body.

1 39. The tissue anchor of claim 39 further comprising an elongate pusher
2 having a fourth locking feature corresponding with the third locking feature of the second
3 anchor body.

1 40. The tissue anchor of claim 30 wherein the corresponding second
2 locking feature is located on a distal end of an elongate pusher.

1 41. The tissue anchor of claim 30 wherein the first locking feature
2 comprises a curved proximal feature adapted to interlock with a corresponding second curved
3 feature.

1 42. The tissue anchor of claim 30 wherein the first locking feature
2 comprises a pin adapted to interlock with a corresponding opening adapted to receive the pin.

1 43. The tissue anchor of claim 30 wherein the first locking feature
2 comprises a coil adapted to wind about a corresponding pin.

1 44. The tissue anchor of claim 30 wherein the first locking feature and
2 corresponding second locking feature comprise an electrolytically erodable joint.

1 45. The tissue anchor of claim 30 wherein the first locking feature and
2 corresponding second locking feature comprise ferromagnets or electromagnets of opposing
3 polarity.

1 46. A method for deploying a tissue anchor in a controlled manner through
2 a lumen, comprising:

3 positioning the lumen relative to a region of tissue to be secured via the tissue
4 anchor;

5 advancing a first anchor body via an elongate pusher through the lumen while
6 maintaining an interlocked orientation between the first anchor body and pusher; and

7 releasing the first anchor body from the pusher upon the first anchor body
8 exiting the lumen.

1 47. The method of claim 47 wherein positioning the lumen comprises
2 advancing the lumen into or through the region of tissue to be secured.

1 48. The method of claim 47 wherein advancing a first anchor body
2 comprises advancing or withdrawing the first anchor body via the elongate pusher through
3 the lumen.

1 49. The method of claim 47 wherein advancing a first anchor body
2 comprises advancing the first anchor body through an arcuate path defined by the lumen.

1 50. The method of claim 47 wherein advancing a first anchor body
2 comprises advancing the first anchor body from the lumen until the first anchor body assumes
3 an expanded deployed configuration.

1 51. The method of claim 47 wherein advancing a first anchor body
2 comprises further advancing a second anchor body via the elongate pusher, wherein the
3 second anchor body is located collinearly distal of the first anchor body within the lumen.

1 52. The method of claim 52 further comprising maintaining an interlocked
2 orientation between the first anchor body and the second anchor body.

1 53. The method of claim 47 wherein releasing the first anchor body from
2 the pusher comprises allowing the first anchor body to fall from the pusher to thereby release
3 the interlocked orientation.

1 54. The method of claim 47 wherein releasing the first anchor body from
2 the pusher comprises energizing an electrolytically erodable joint between the first anchor
3 body and the pusher.

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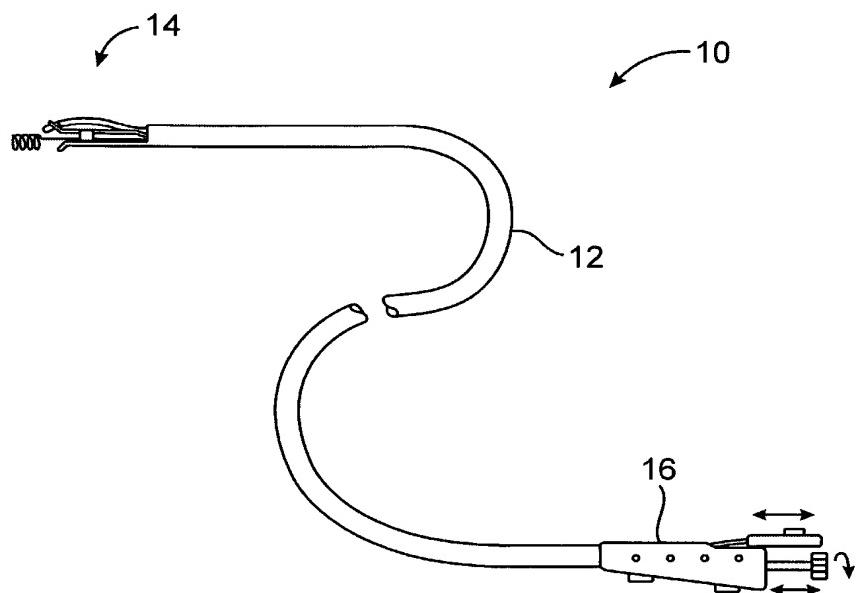


FIG. 1A

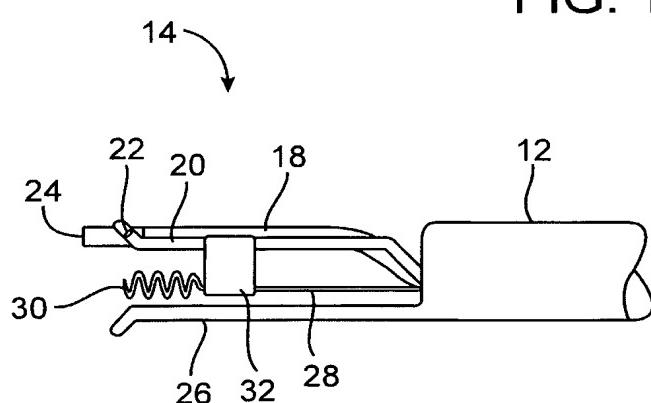


FIG. 1B

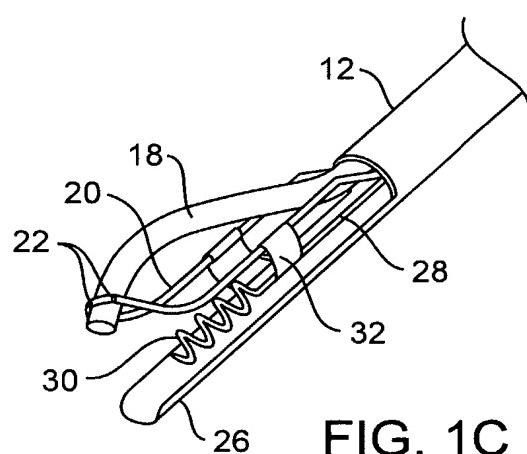


FIG. 1C

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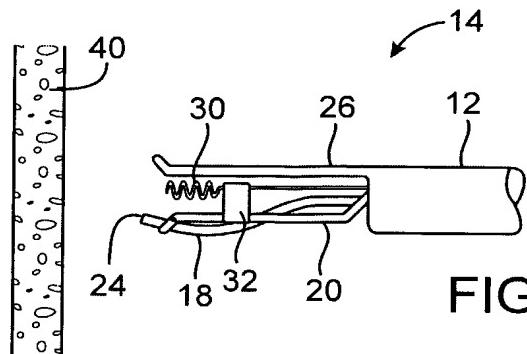


FIG. 2A

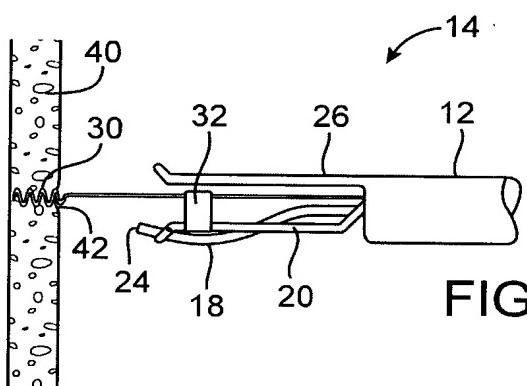


FIG. 2B

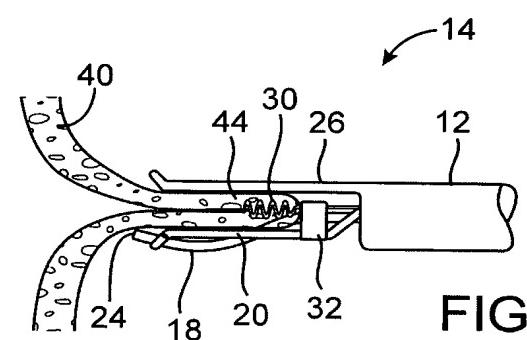


FIG. 2C

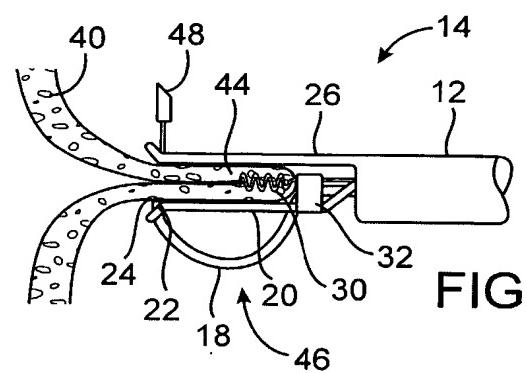


FIG. 2D

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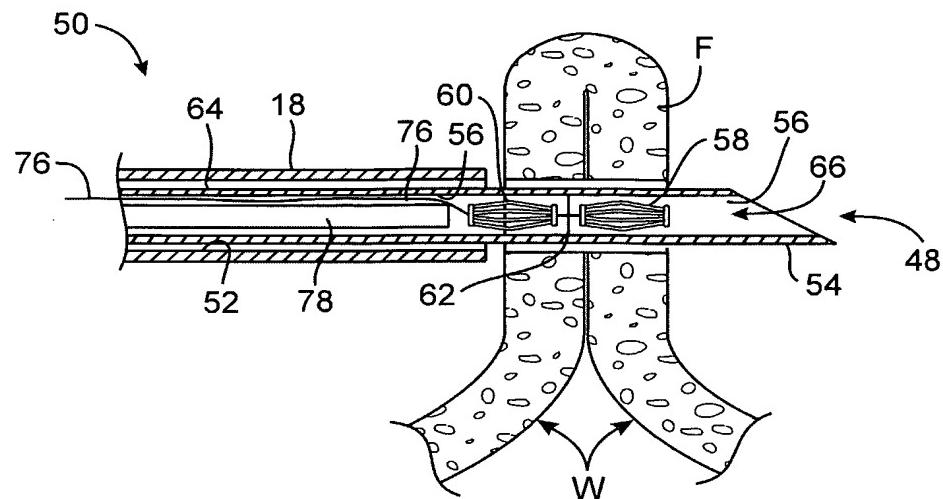


FIG. 3A

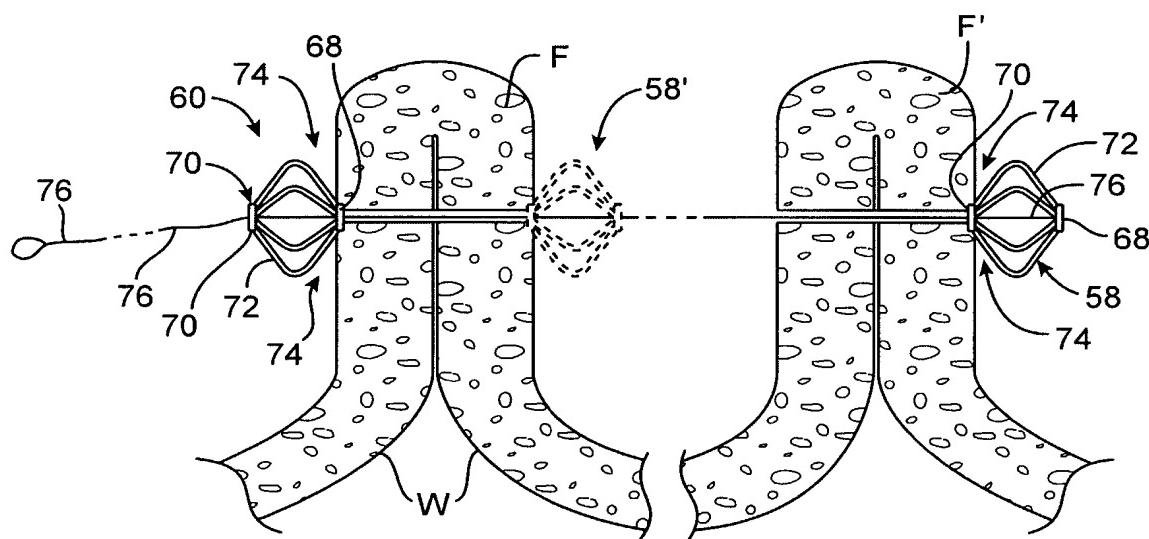


FIG. 3B

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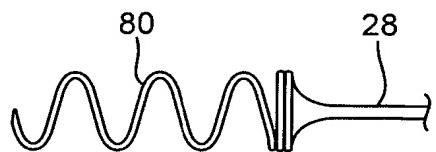


FIG. 4A

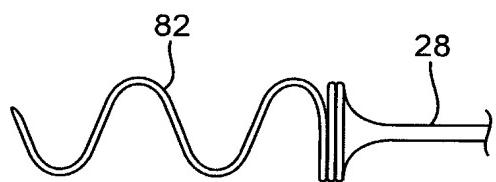


FIG. 4B

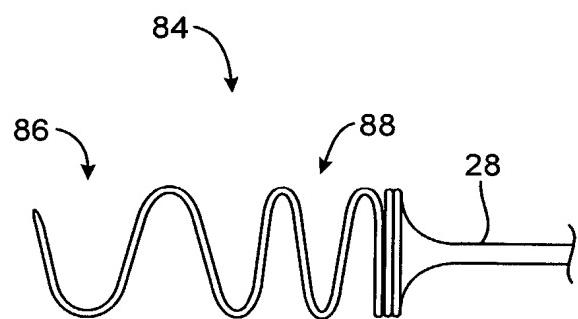


FIG. 4C

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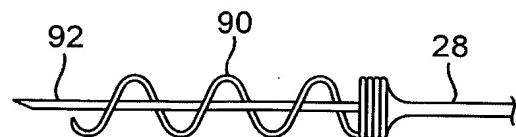


FIG. 4D

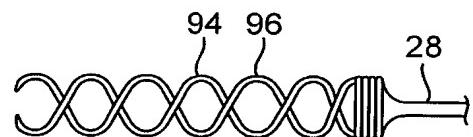


FIG. 4E

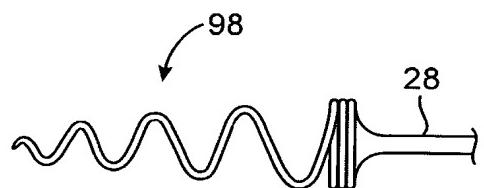


FIG. 4F

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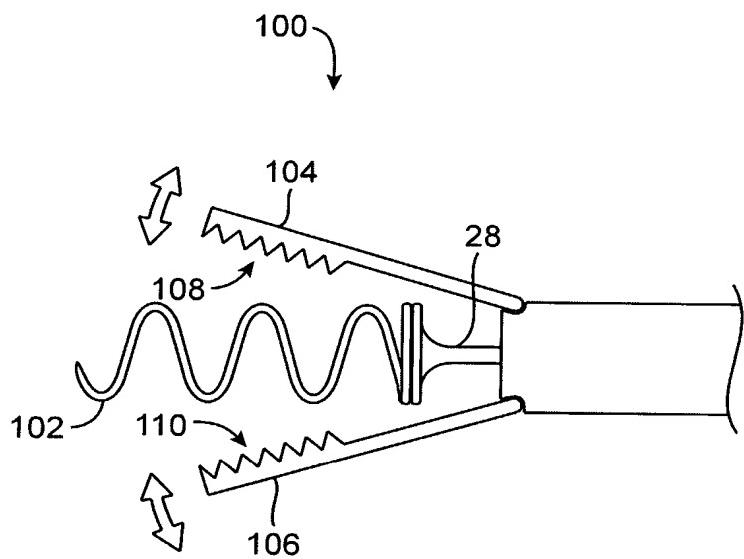


FIG. 4G

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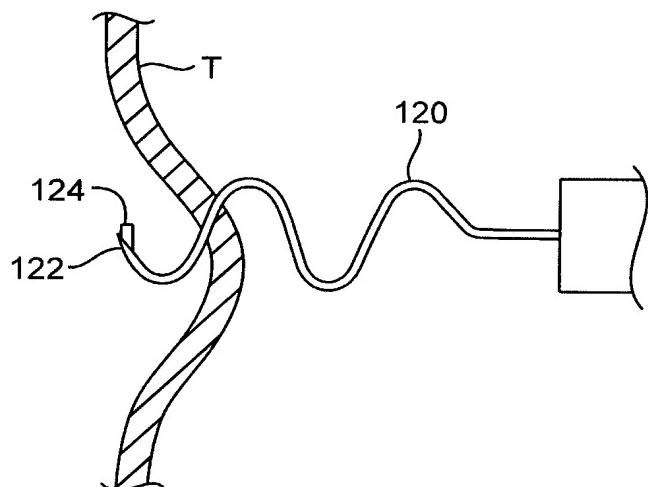


FIG. 5A

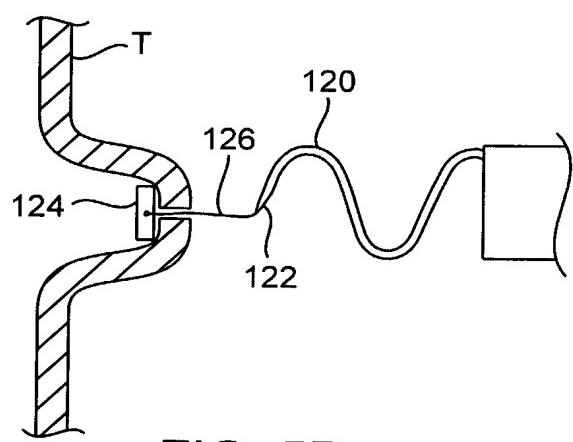


FIG. 5B

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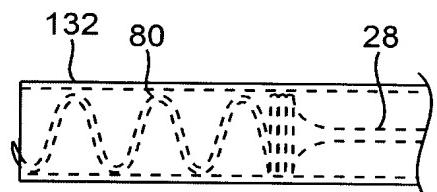
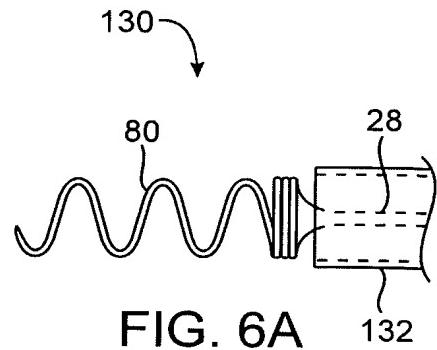


FIG. 6B

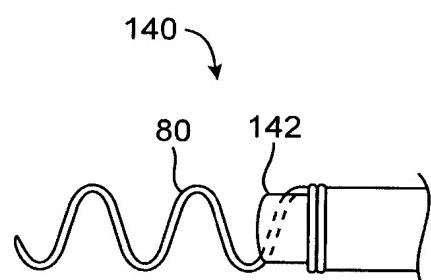


FIG. 7A

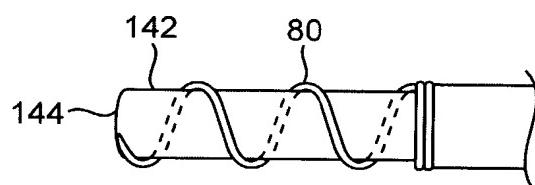


FIG. 7B

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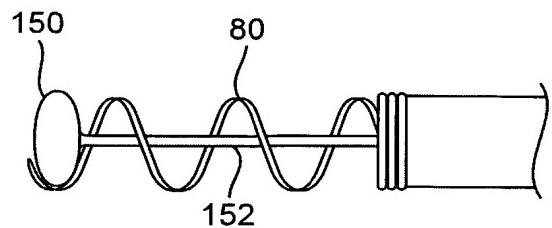


FIG. 8

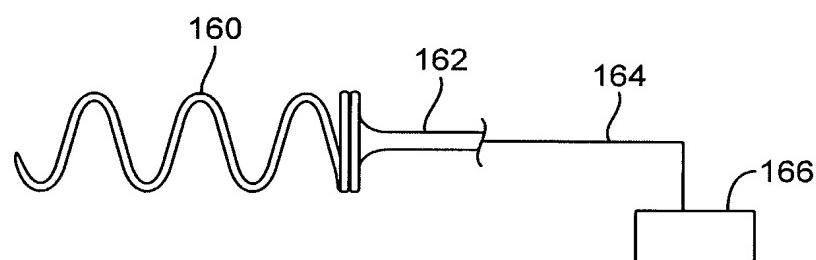


FIG. 9A

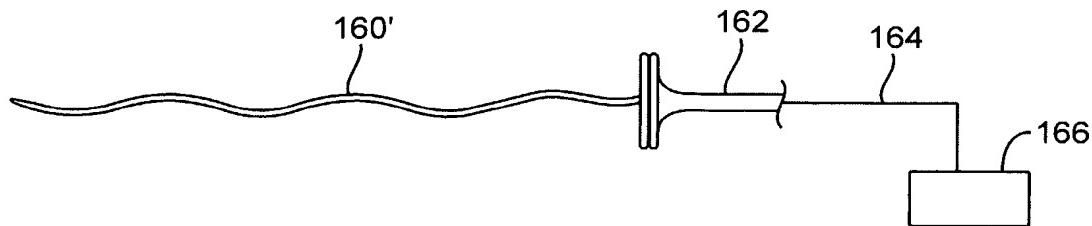


FIG. 9B

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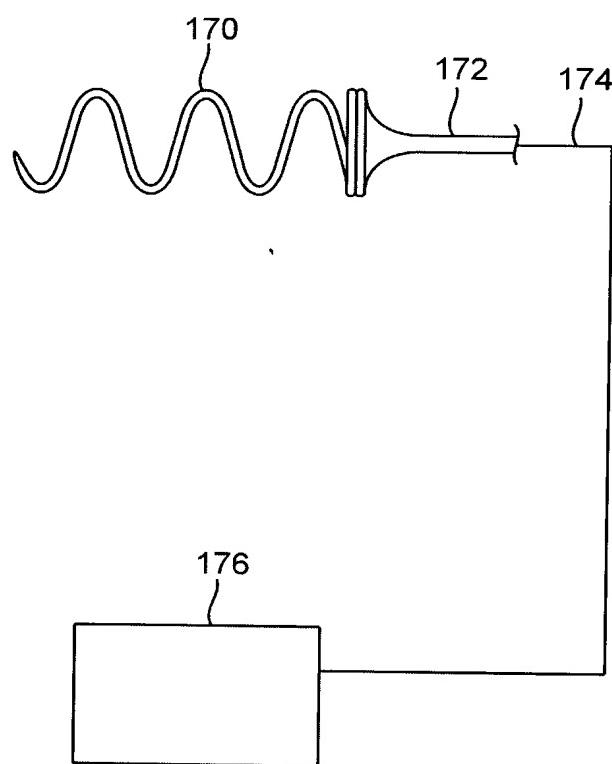


FIG. 10

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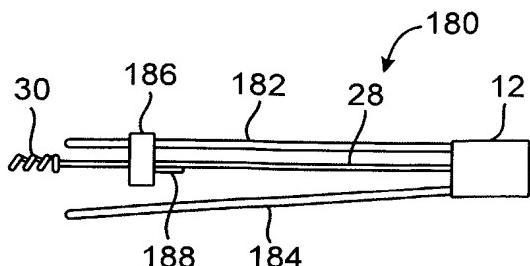


FIG. 11A

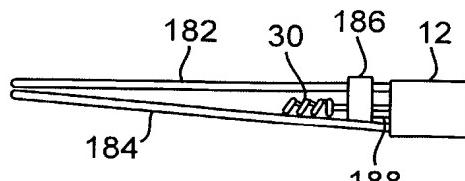


FIG. 11B

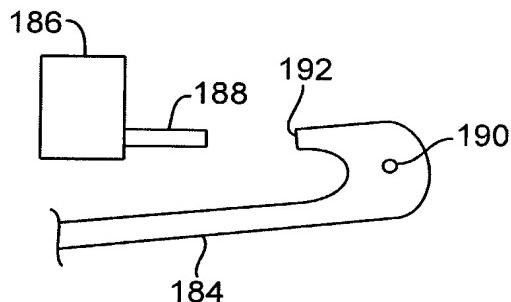


FIG. 11C

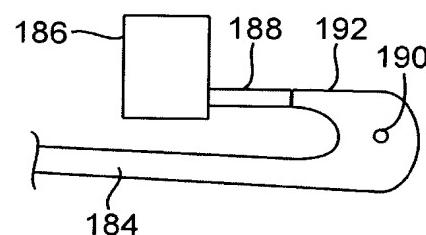


FIG. 11D

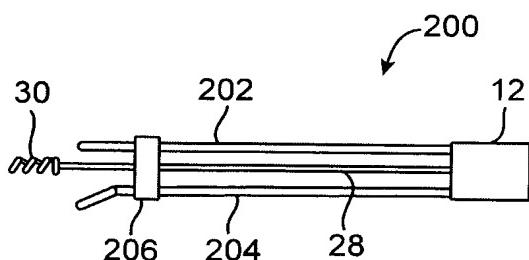


FIG. 12A

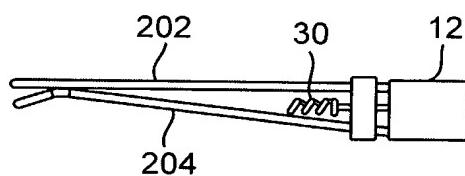


FIG. 12B

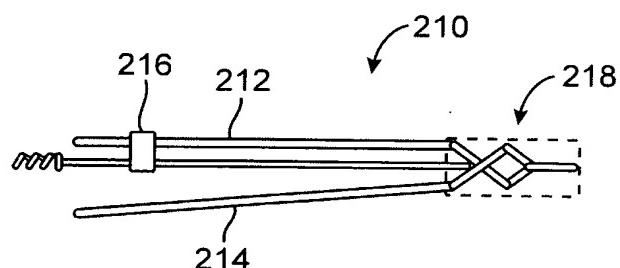


FIG. 13A

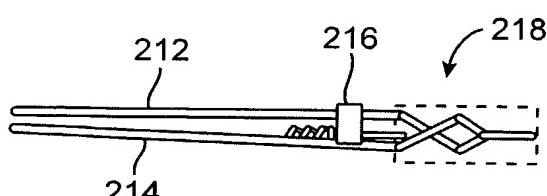


FIG. 13B

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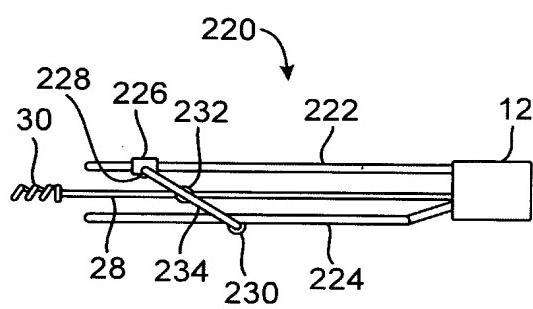


FIG. 14A

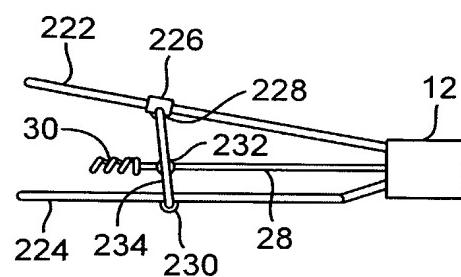


FIG. 14B

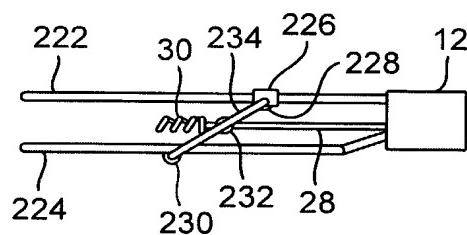


FIG. 14C

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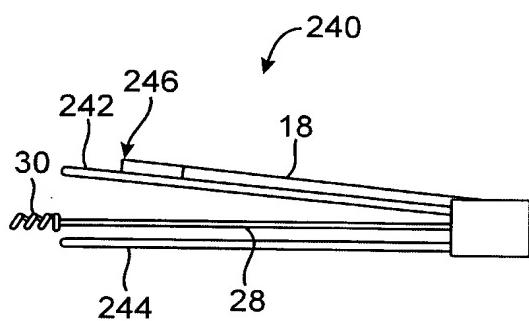


FIG. 15A

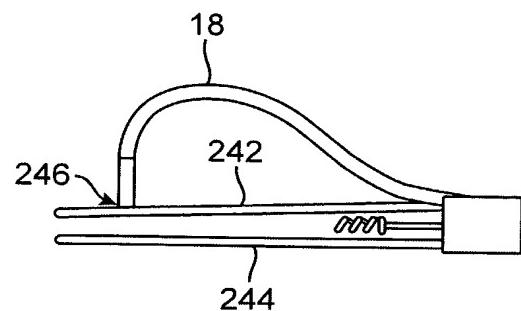


FIG. 15B

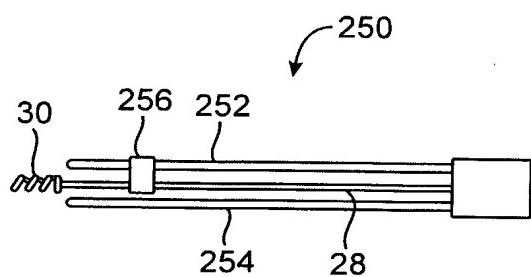


FIG. 16A

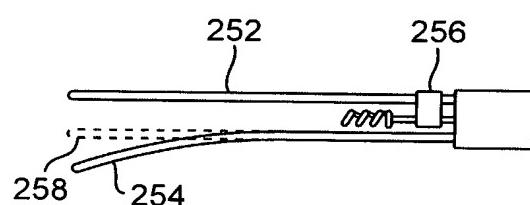


FIG. 16B

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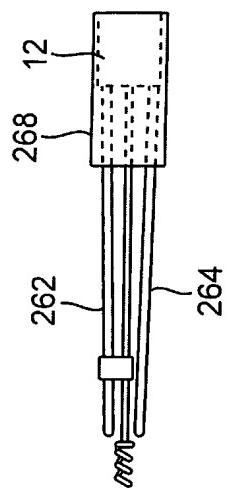


FIG. 17B

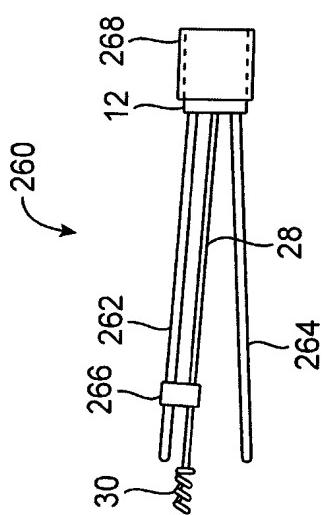


FIG. 17A

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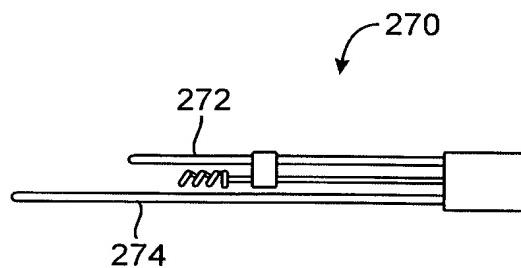


FIG. 18

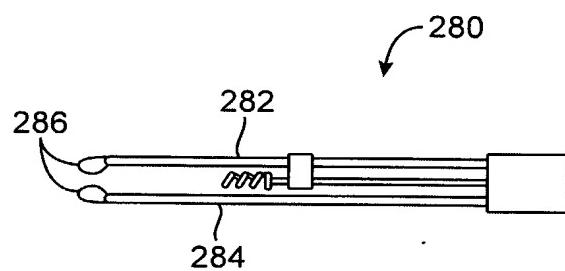


FIG. 19

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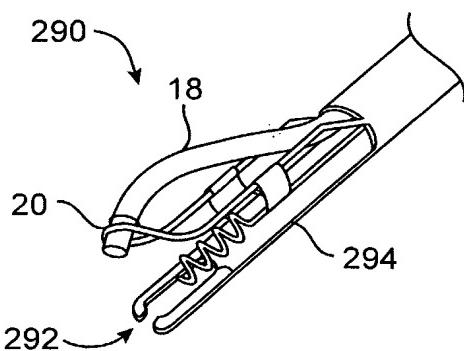


FIG. 20A

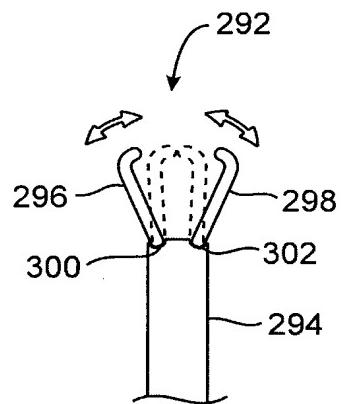


FIG. 20B

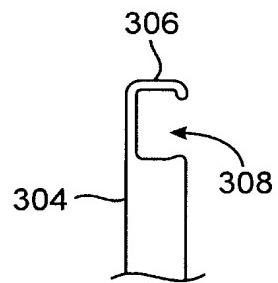


FIG. 20C

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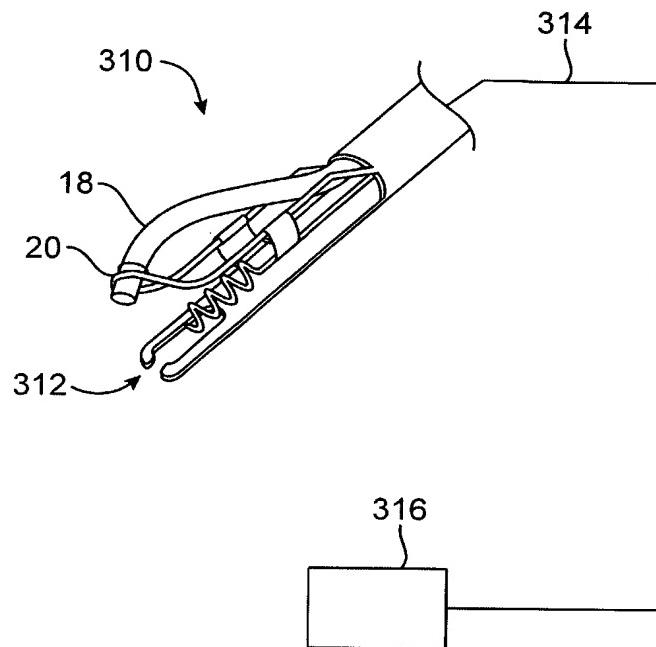


FIG. 21A

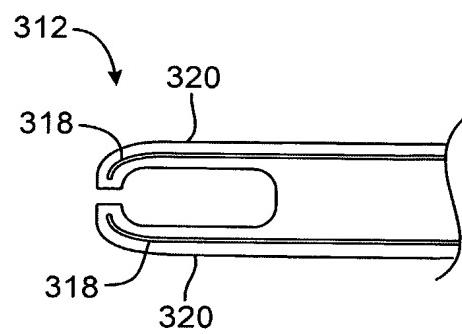
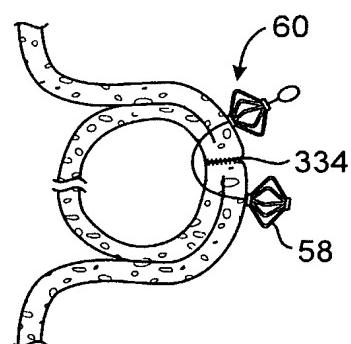
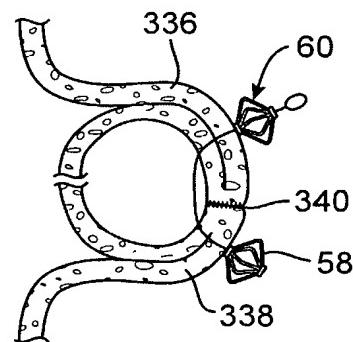
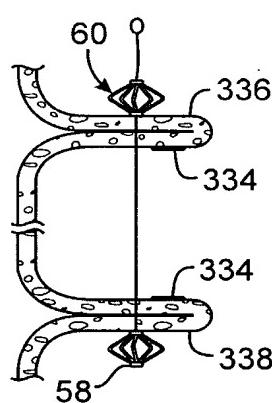
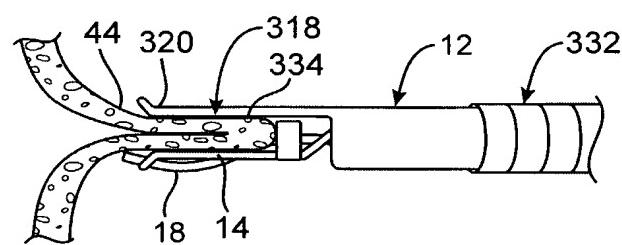
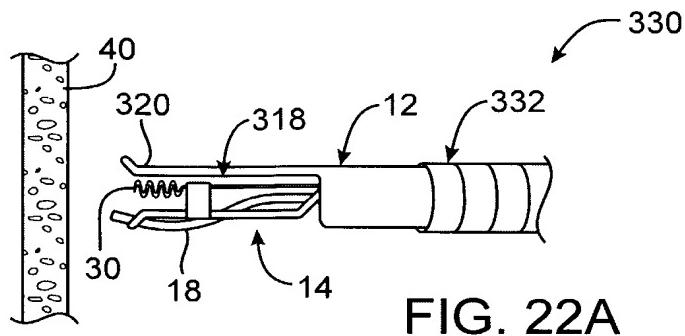


FIG. 21B

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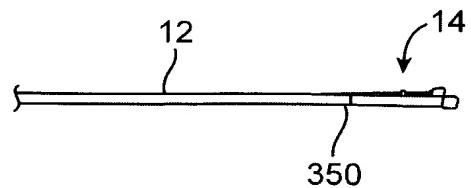


FIG. 23A

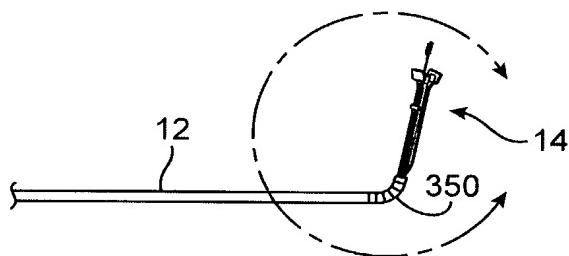


FIG. 23B

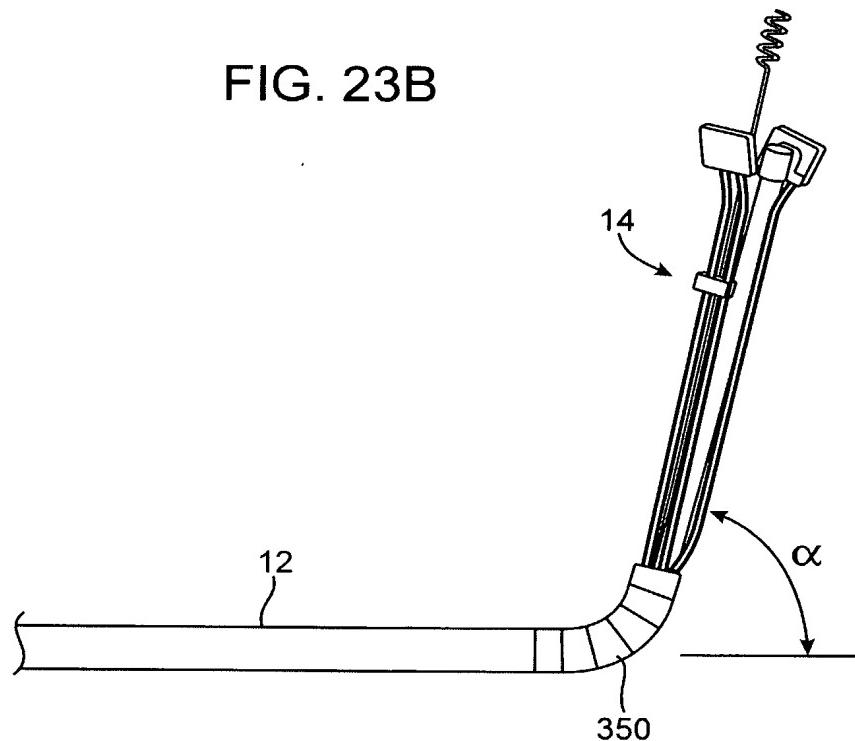


FIG. 23C

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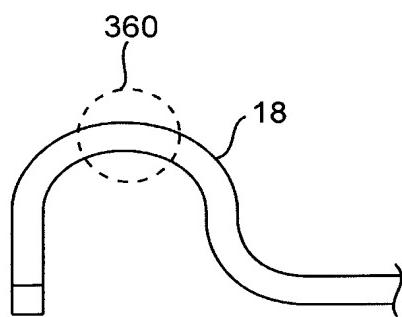


FIG. 24A

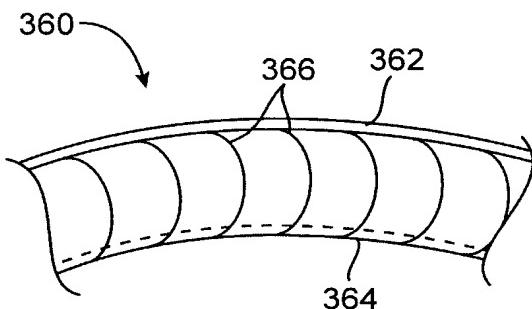


FIG. 24B

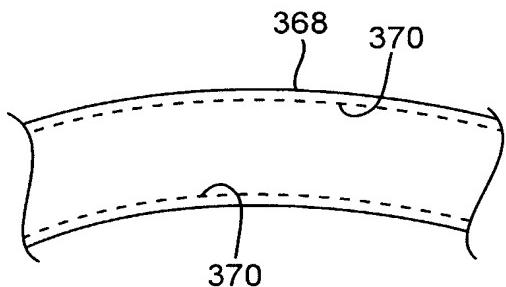


FIG. 24C

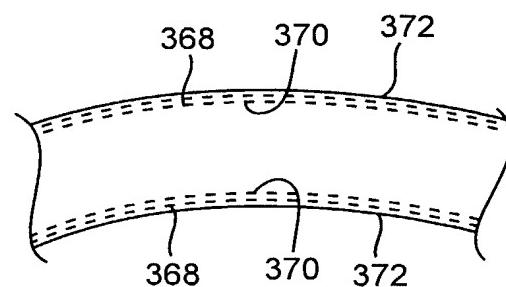


FIG. 24D

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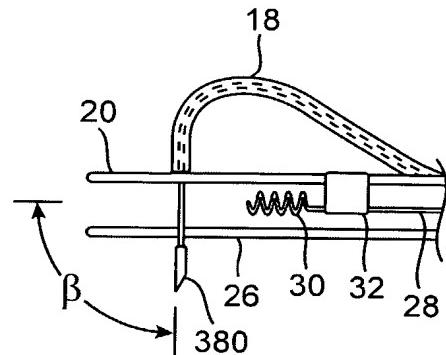


FIG. 25

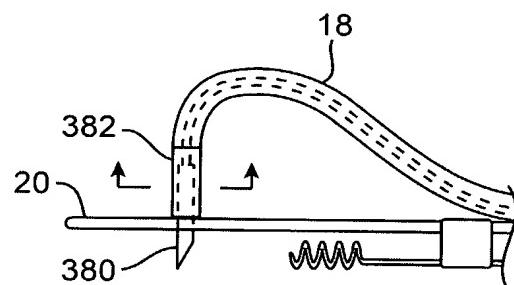


FIG. 26A

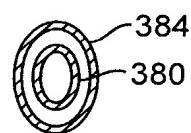


FIG. 26B

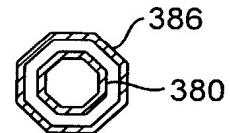


FIG. 26C

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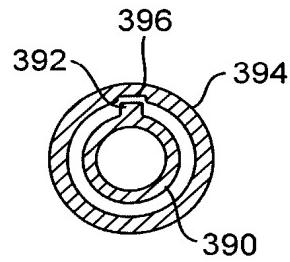


FIG. 27A

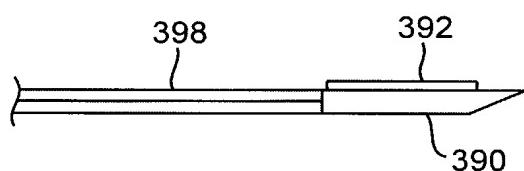


FIG. 27B

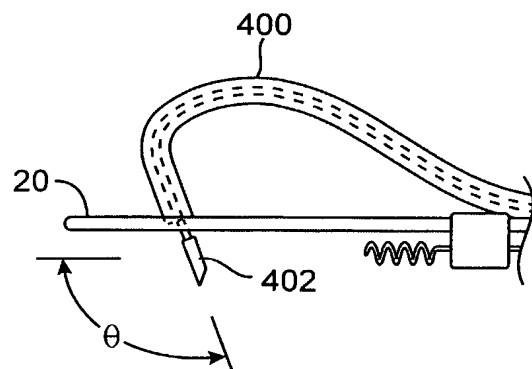


FIG. 28

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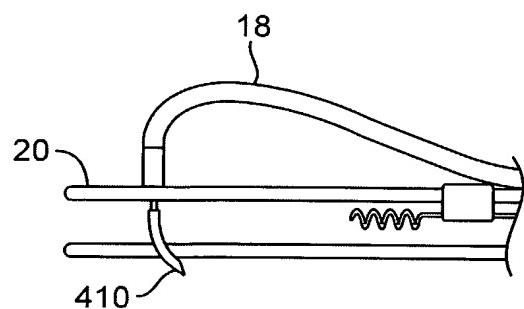


FIG. 29A

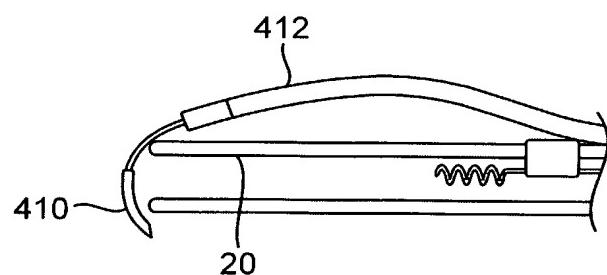


FIG. 29B

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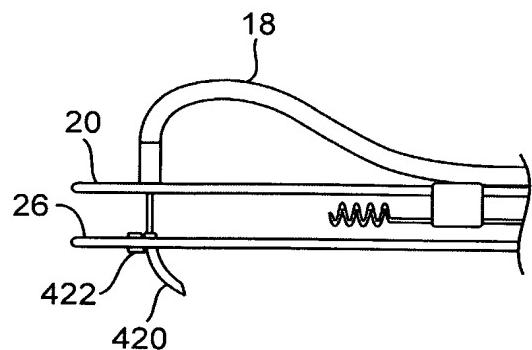


FIG. 30

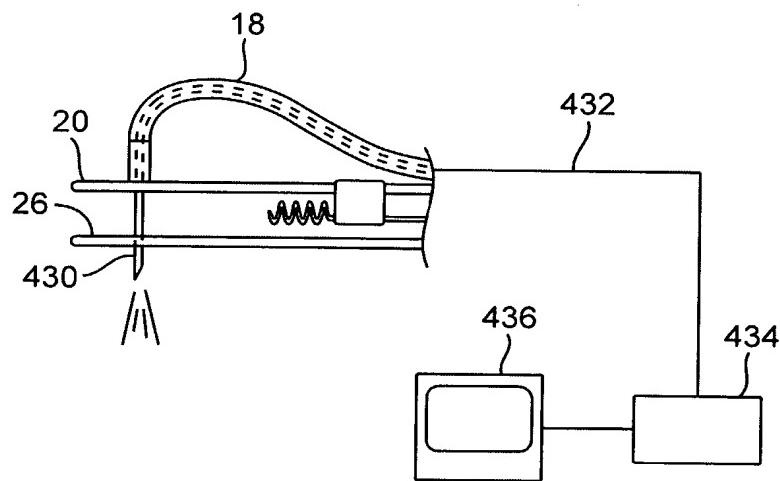


FIG. 31

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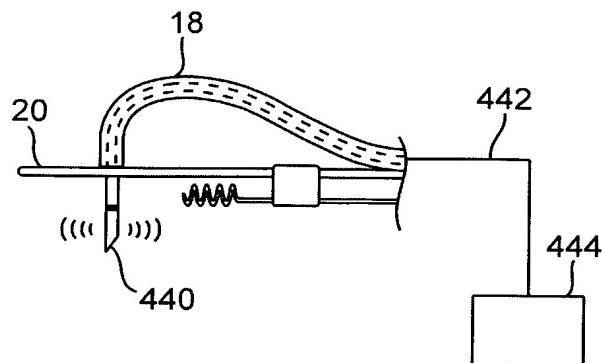


FIG. 32

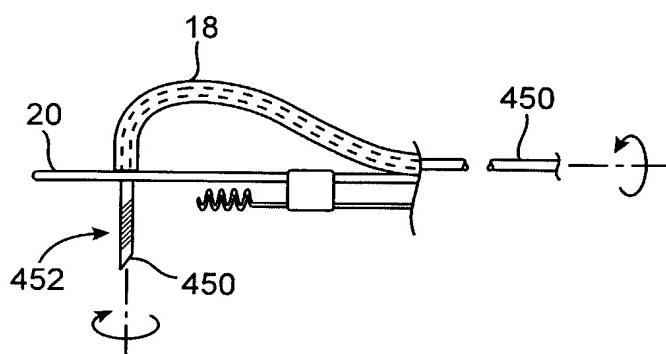


FIG. 33

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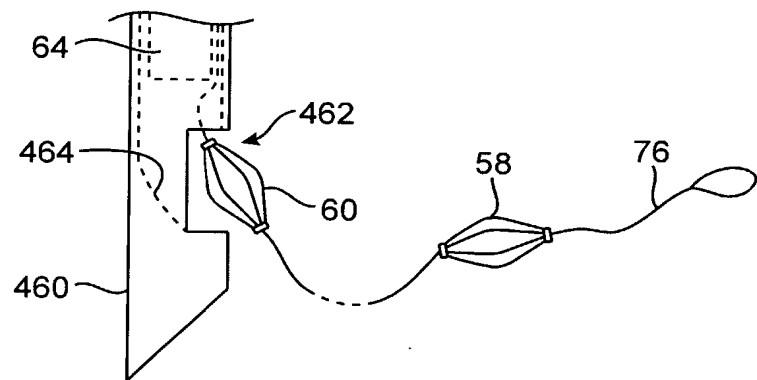


FIG. 34A

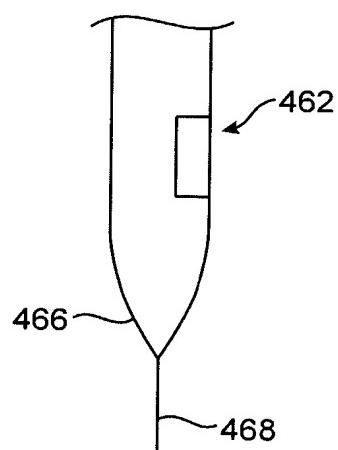


FIG. 34B

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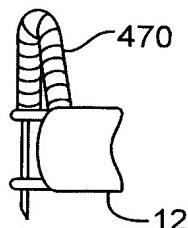


FIG. 35B

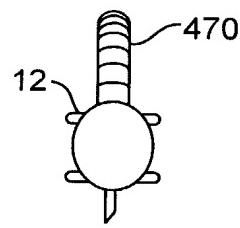


FIG. 35A

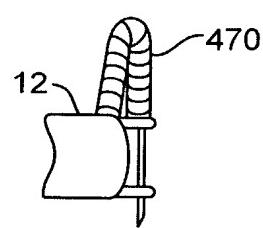


FIG. 35C

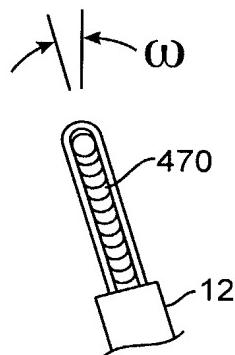


FIG. 36B

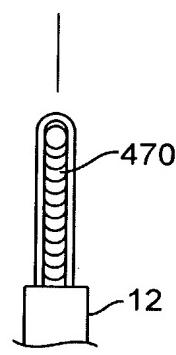


FIG. 36A

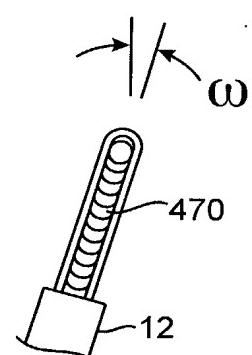


FIG. 36C

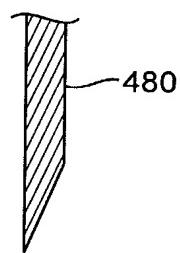


FIG. 37A

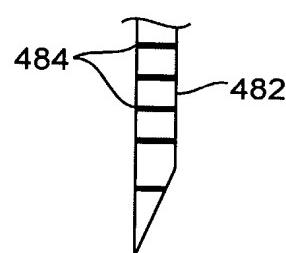


FIG. 37B

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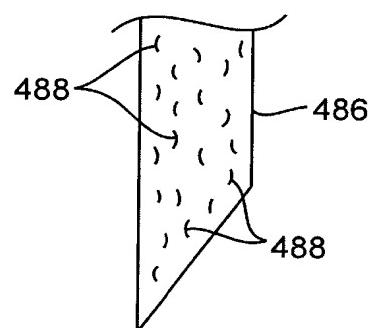


FIG. 37C

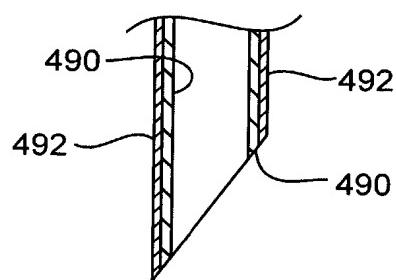


FIG. 37D

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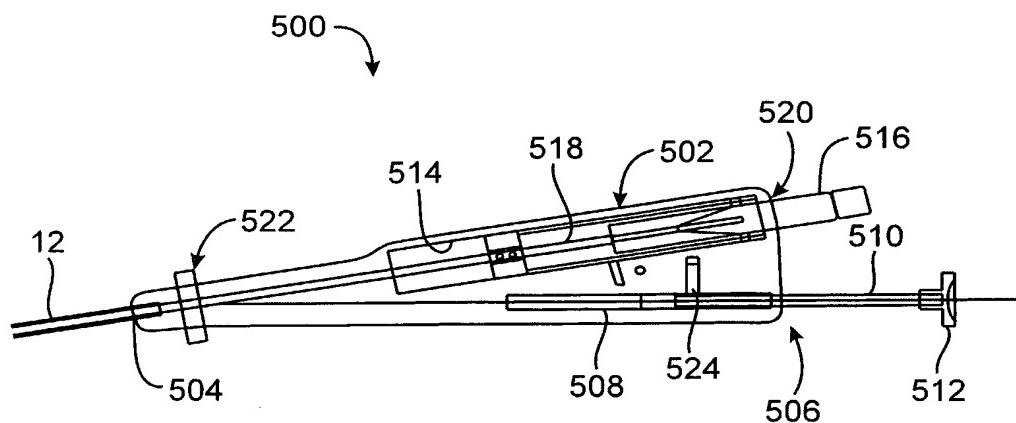


FIG. 38A

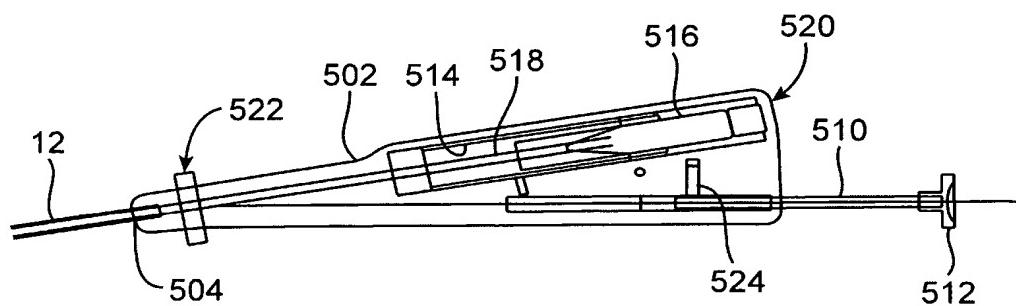


FIG. 38B

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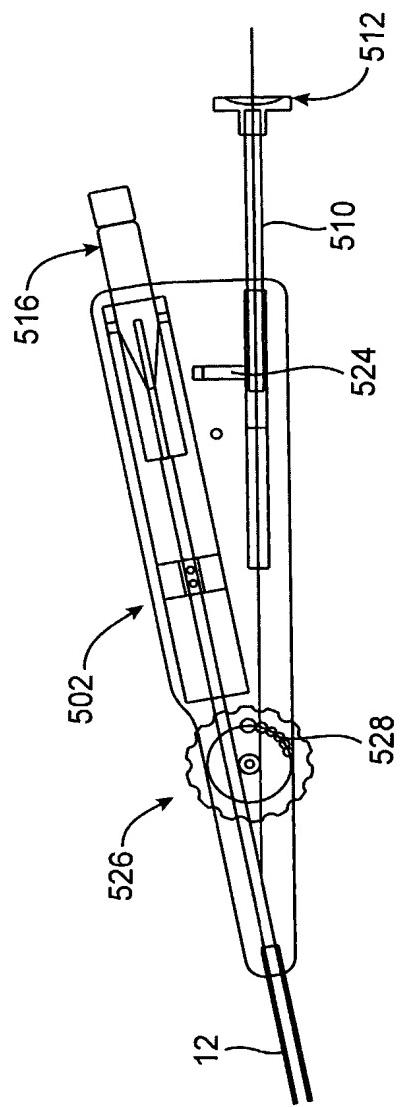


FIG. 38C

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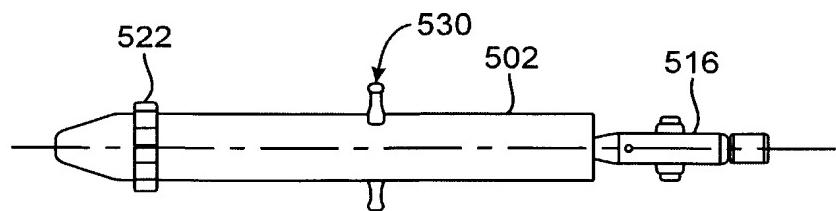


FIG. 39A

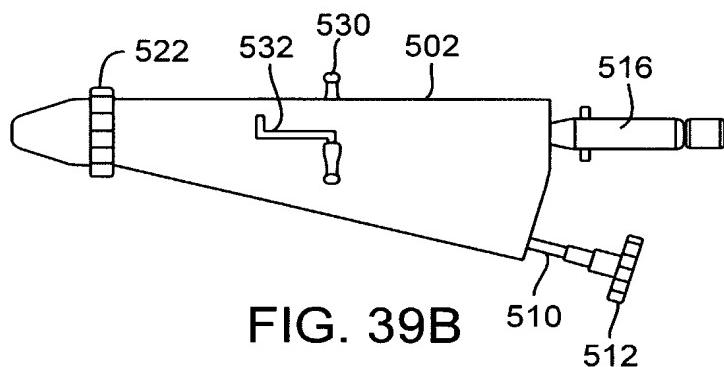


FIG. 39B

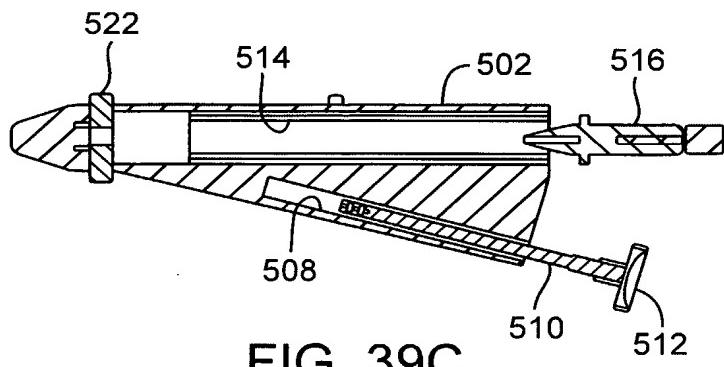


FIG. 39C

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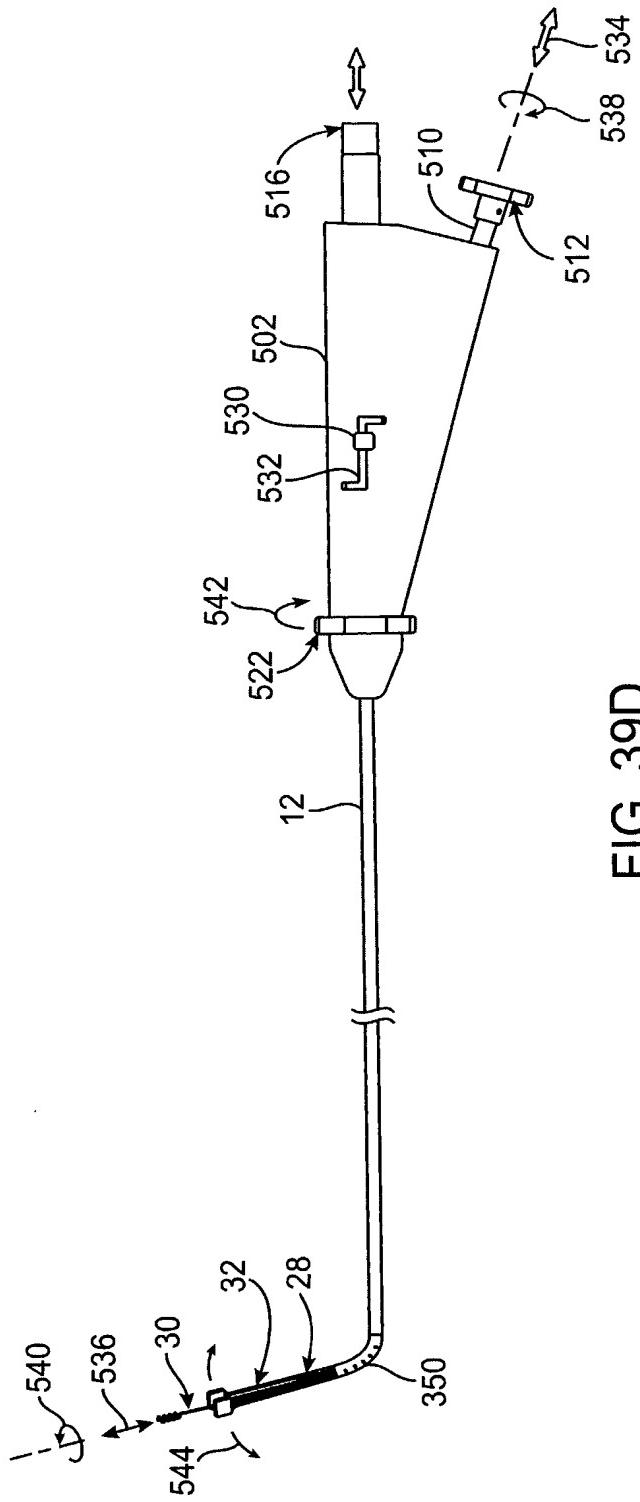


FIG. 39D

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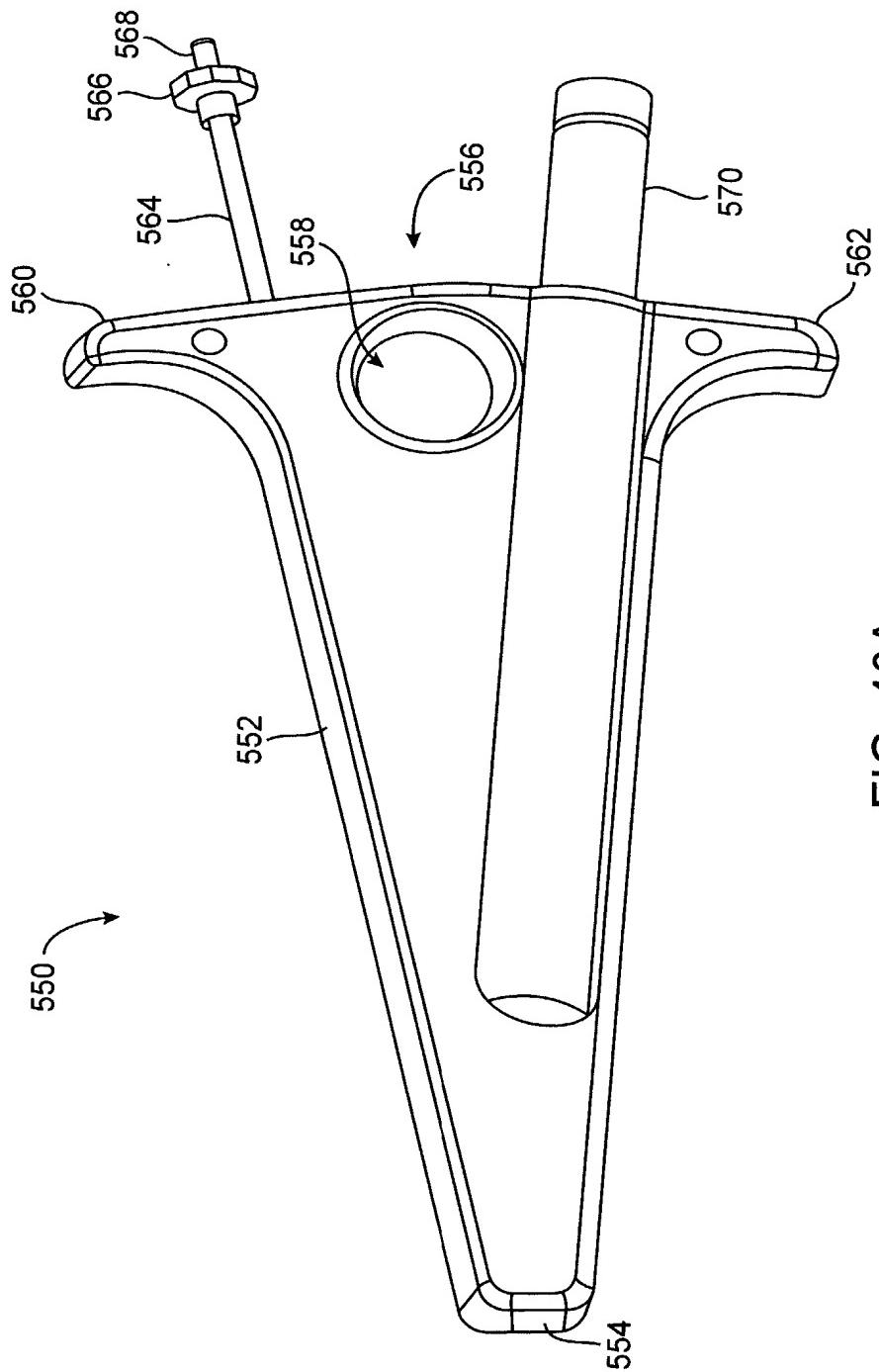


FIG. 40A

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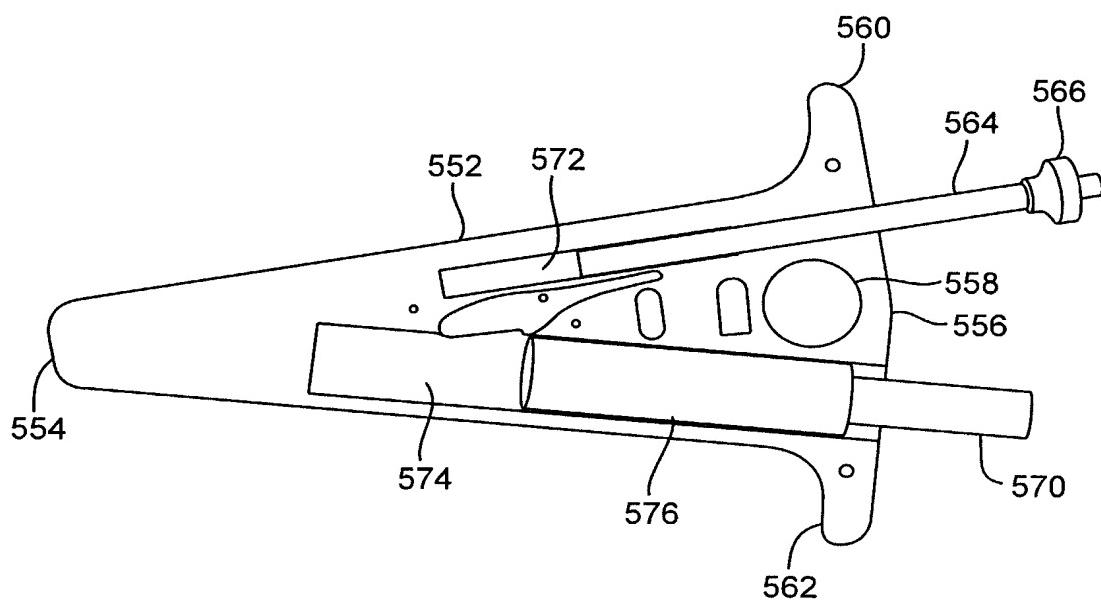


FIG. 40B

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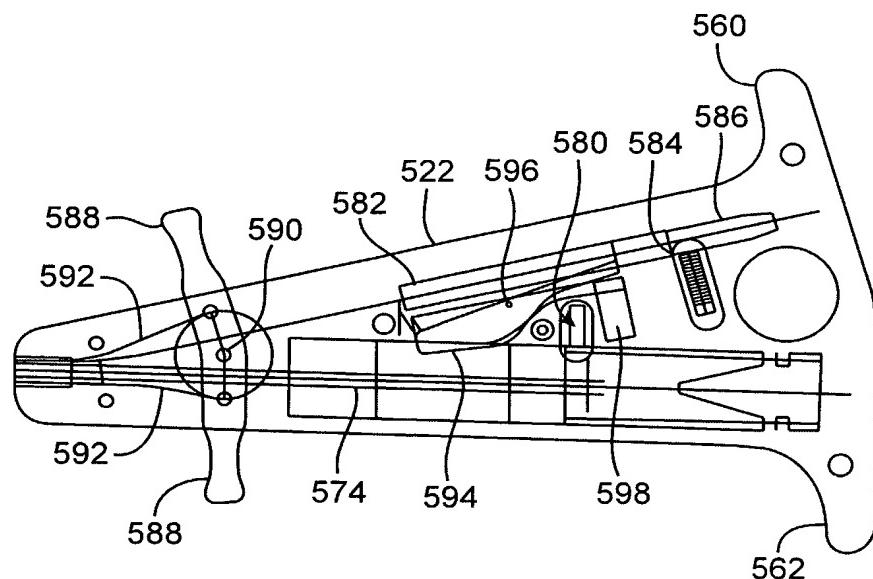


FIG. 41A

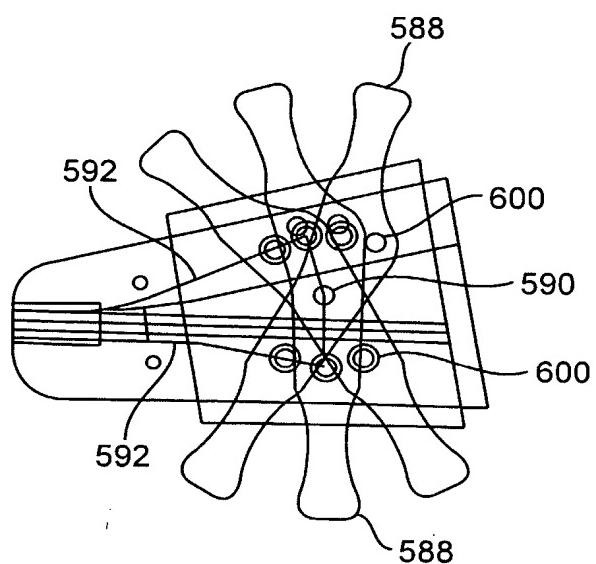


FIG. 41B

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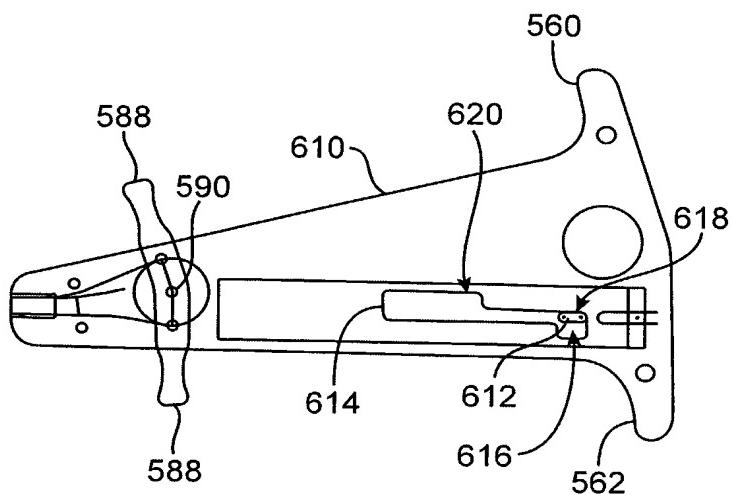


FIG. 42A

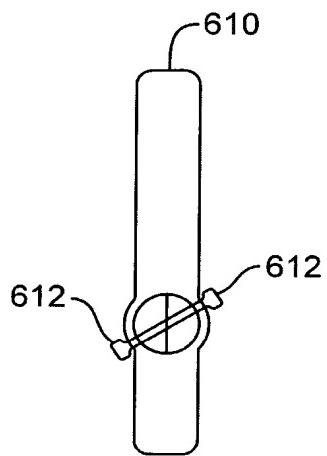


FIG. 42B

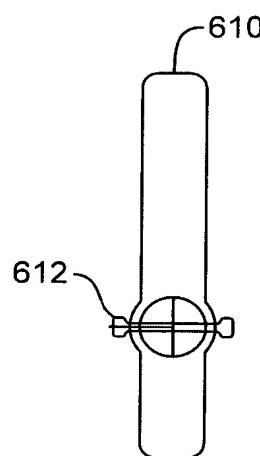


FIG. 42C

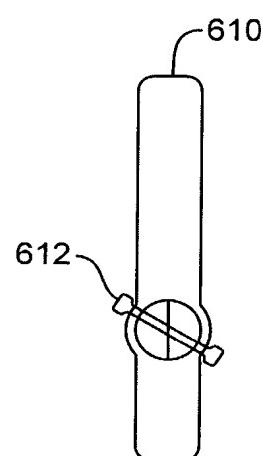


FIG. 42D

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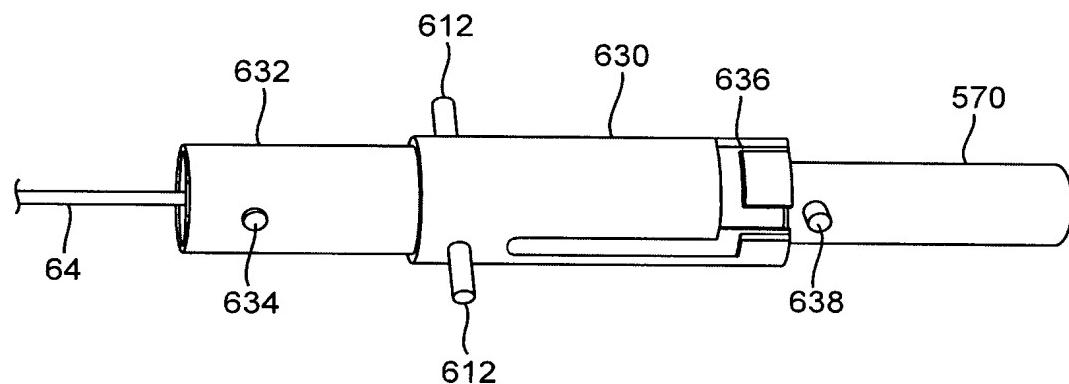


FIG. 43A

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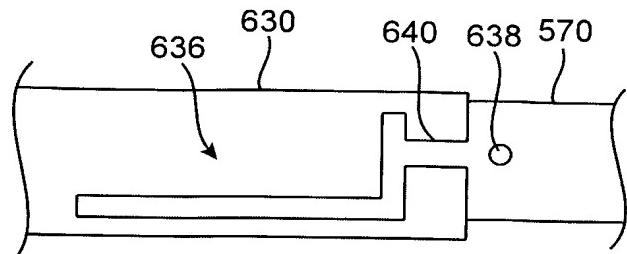


FIG. 43B

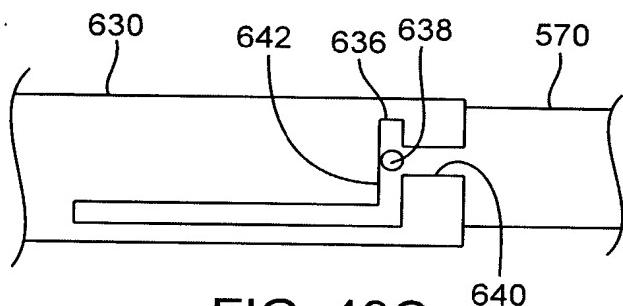


FIG. 43C

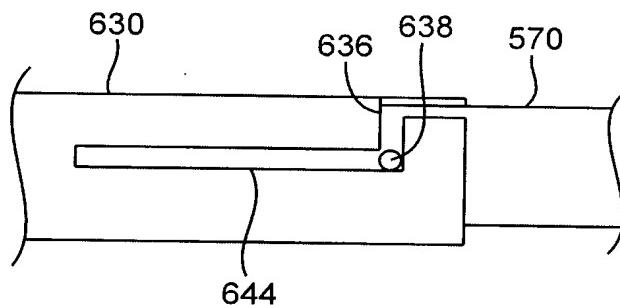


FIG. 43D

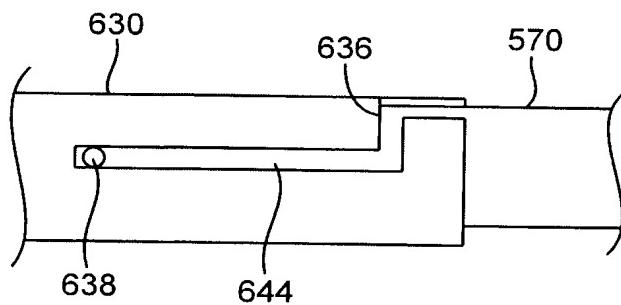


FIG. 43E

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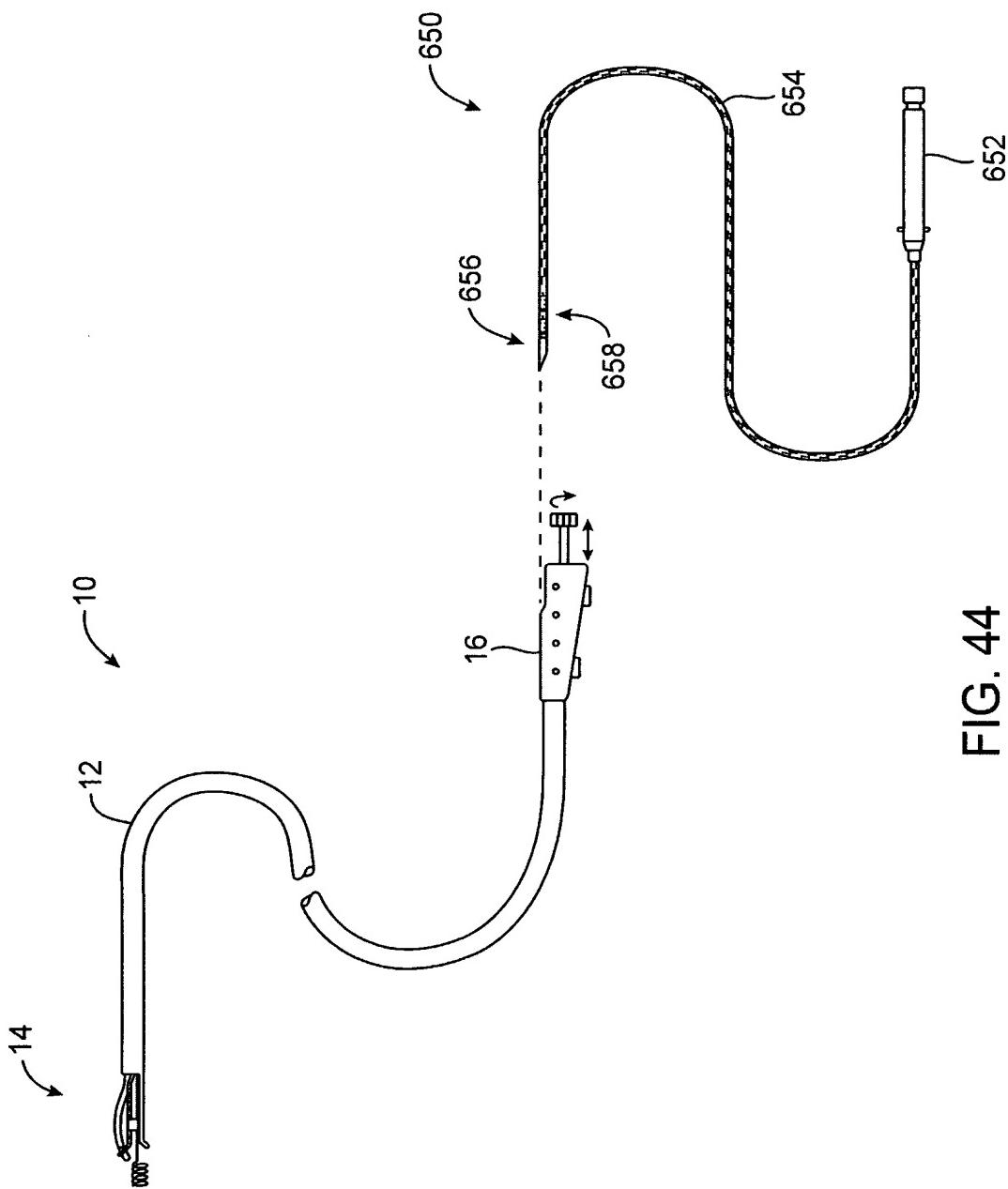


FIG. 44

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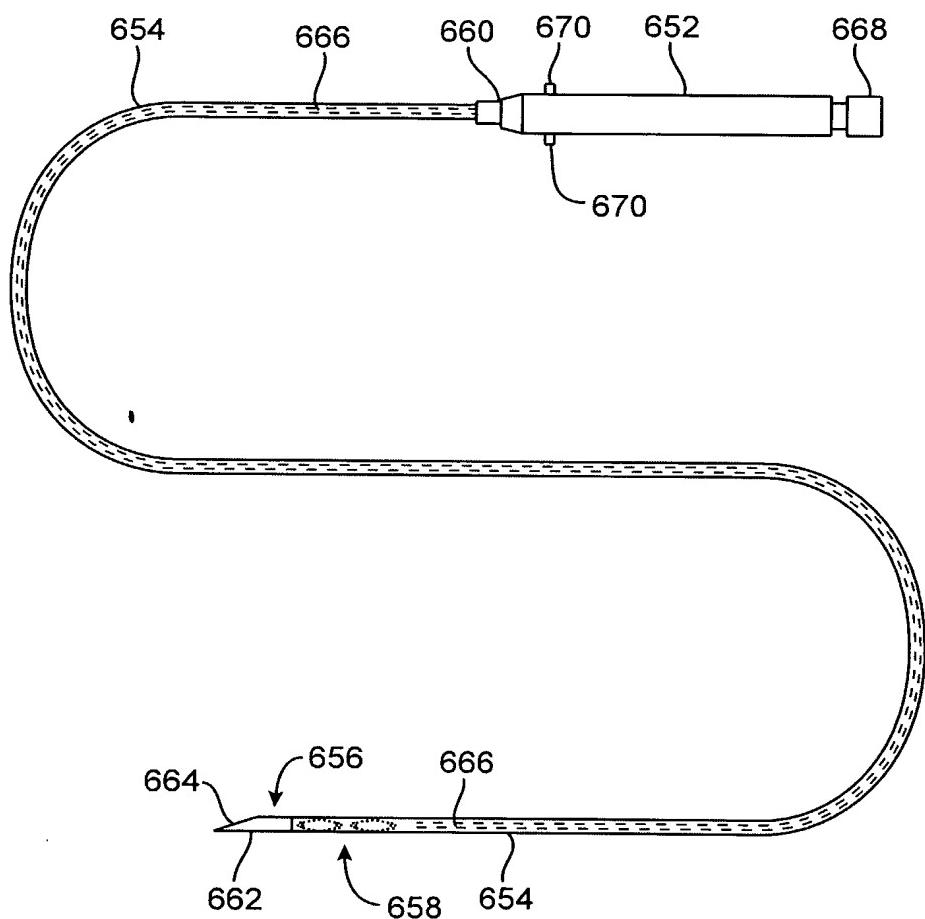


FIG. 45A

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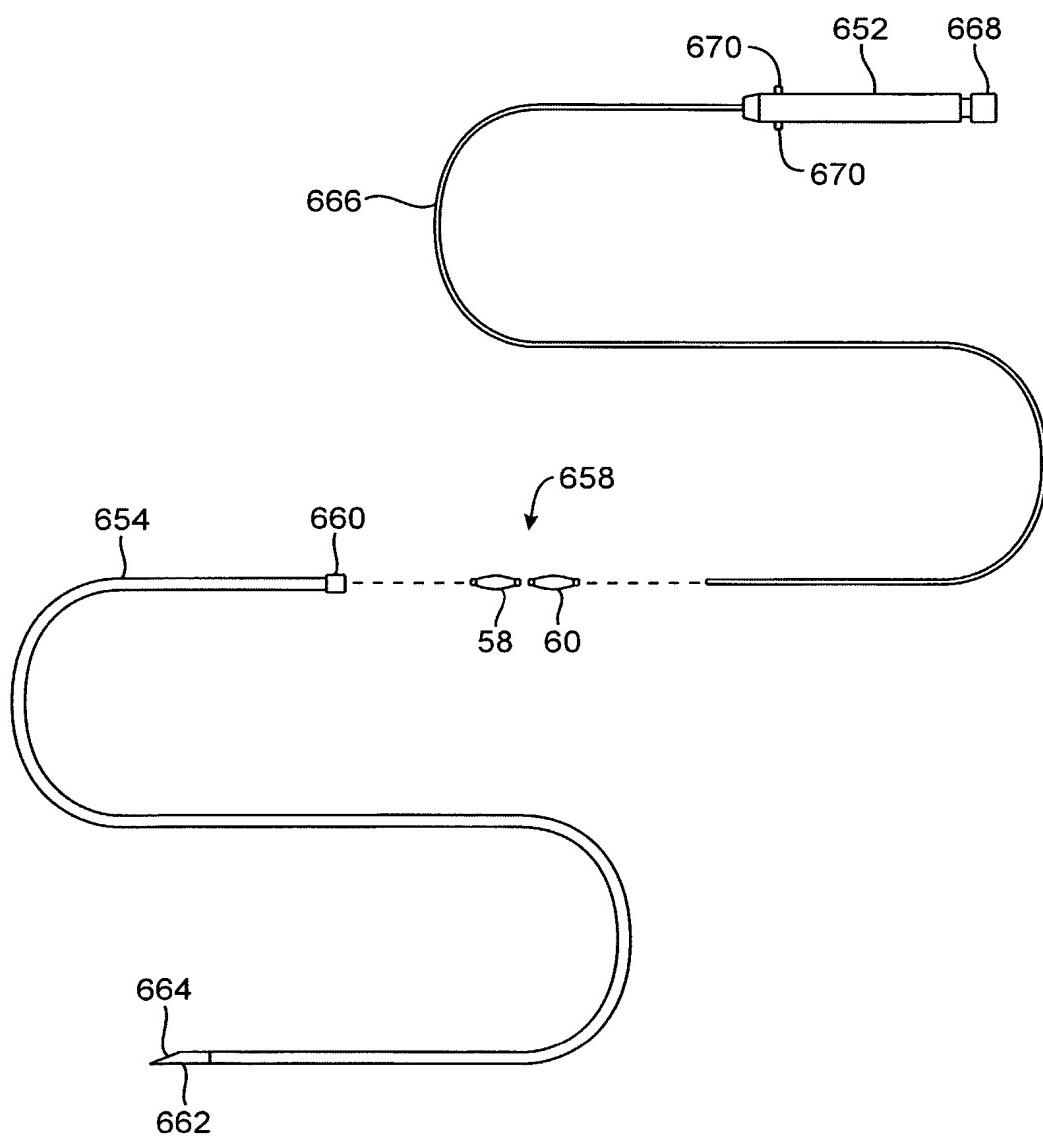


FIG. 45B

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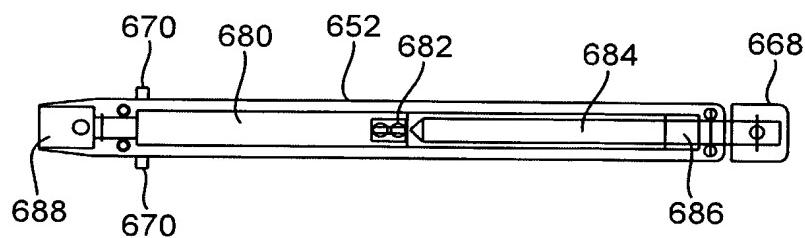


FIG. 46A

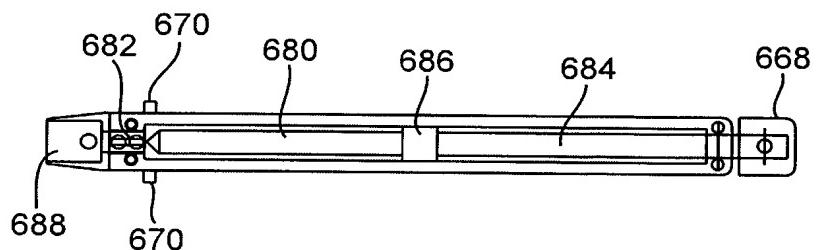


FIG. 46B

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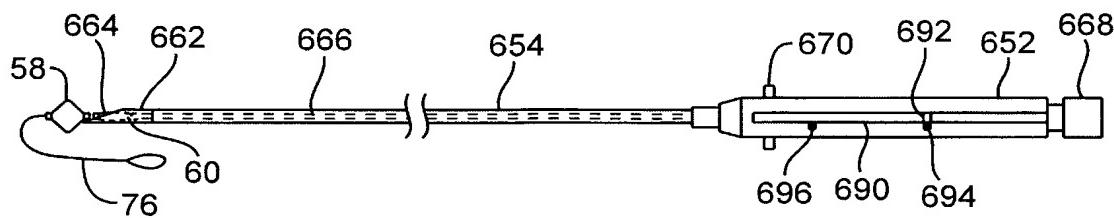


FIG. 47A

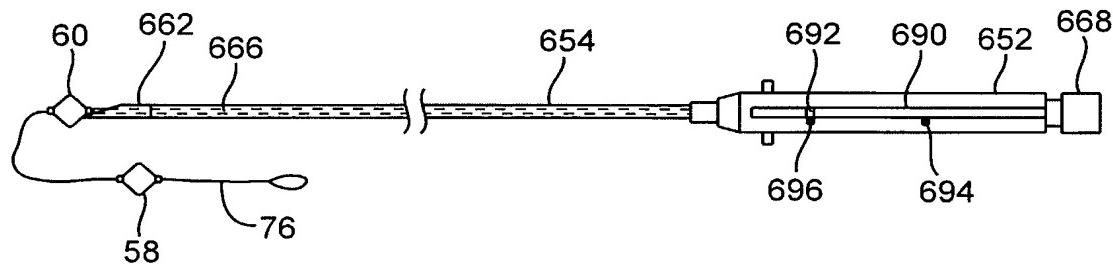


FIG. 47B

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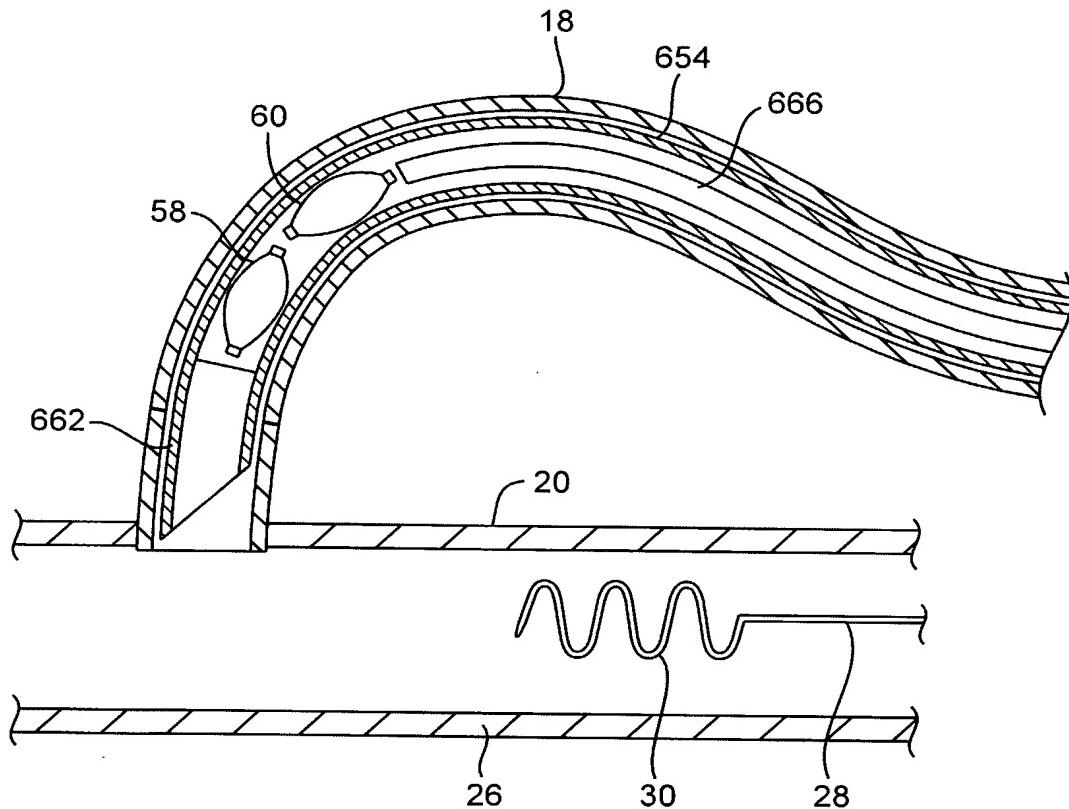


FIG. 47C

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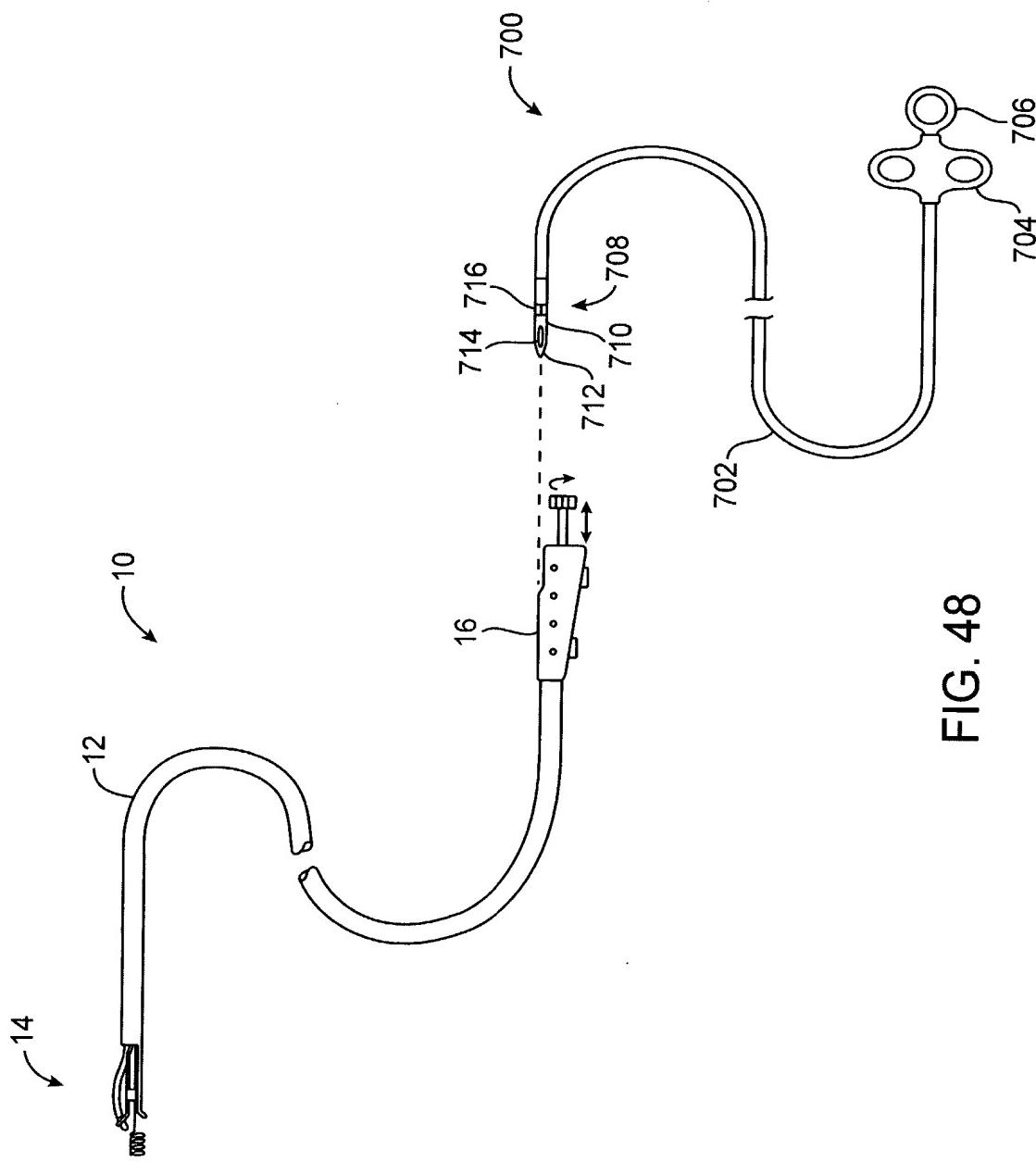


FIG. 48

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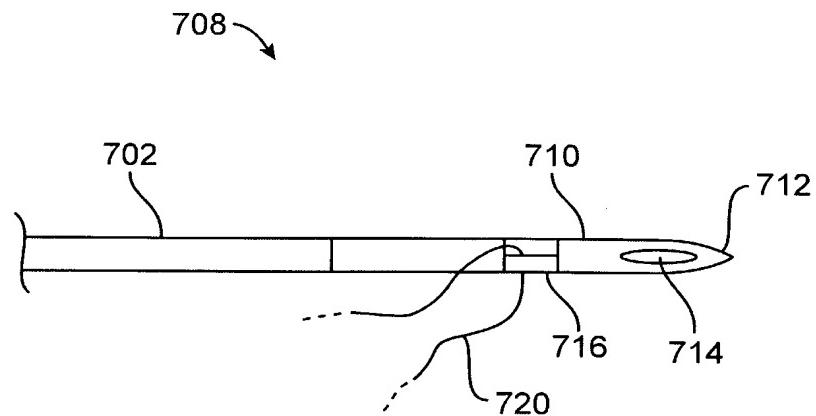


FIG. 49A

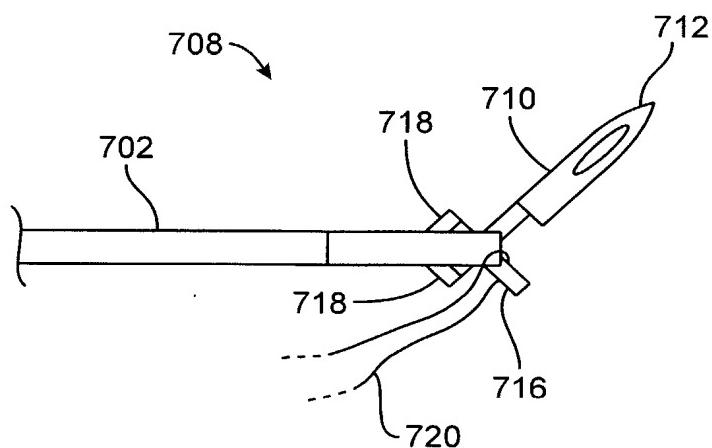


FIG. 49B

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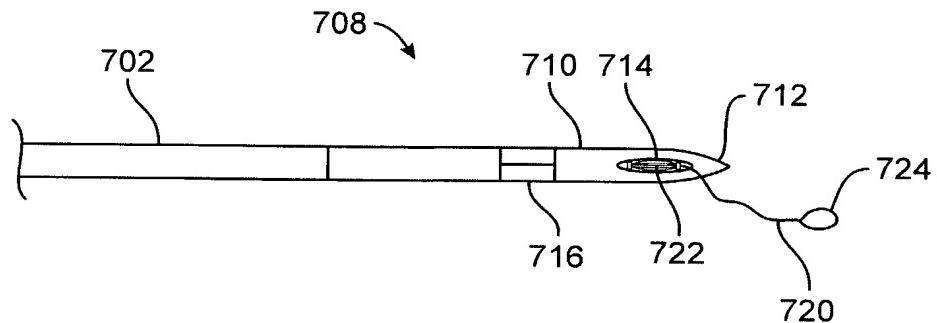


FIG. 50A

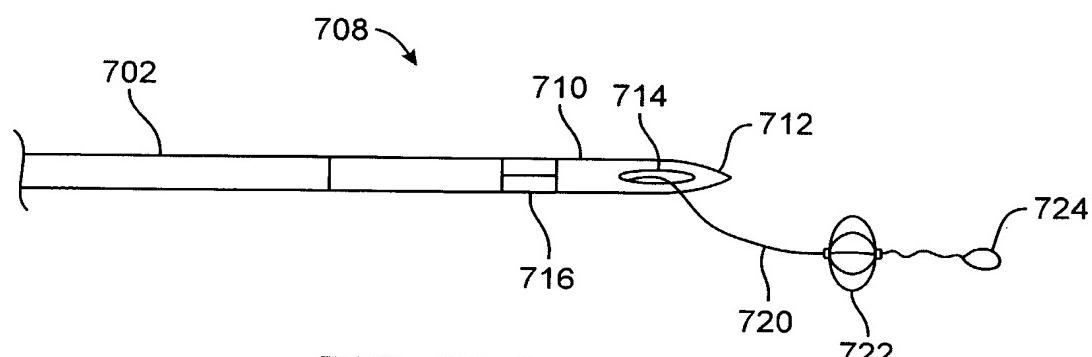


FIG. 50B

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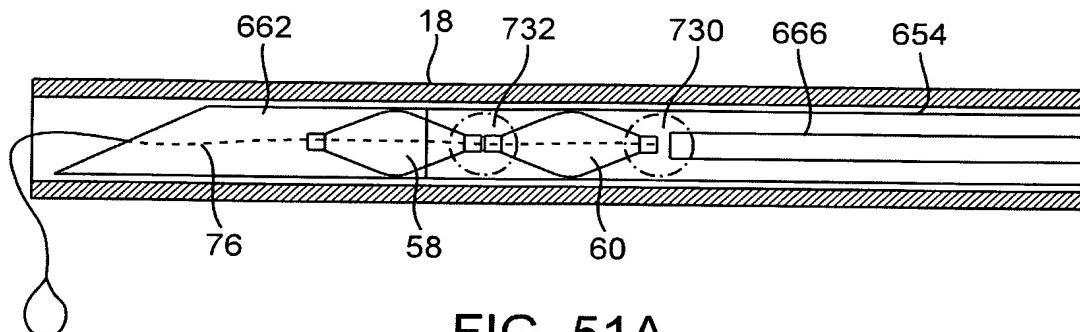


FIG. 51A

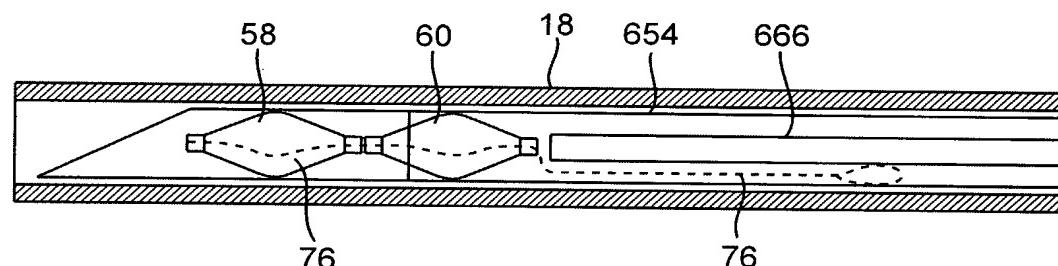


FIG. 51B

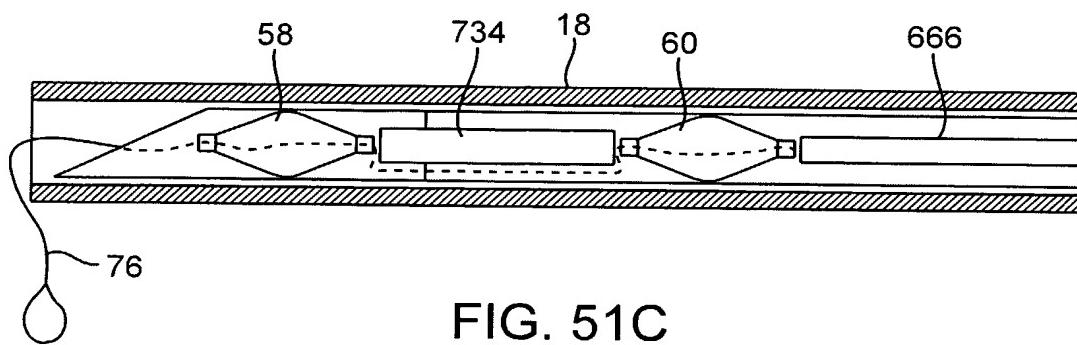


FIG. 51C

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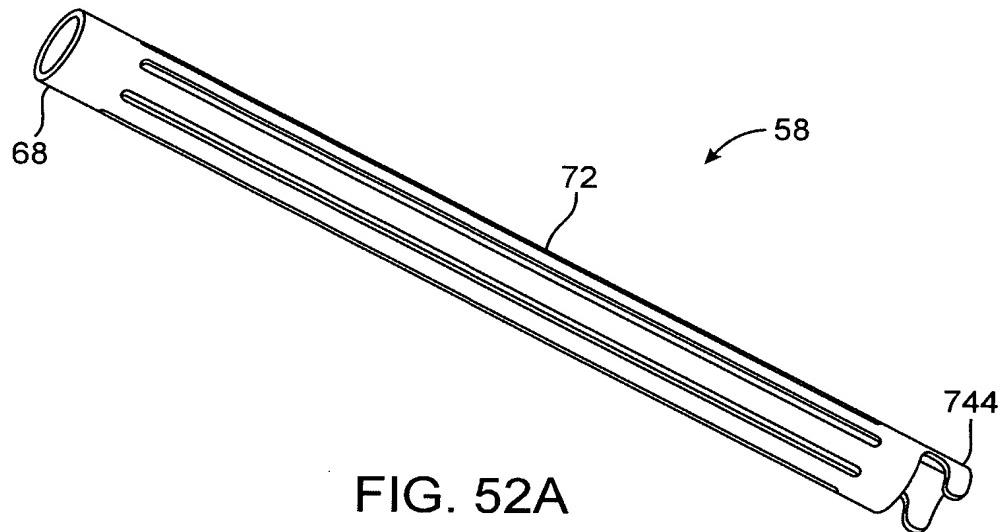


FIG. 52A

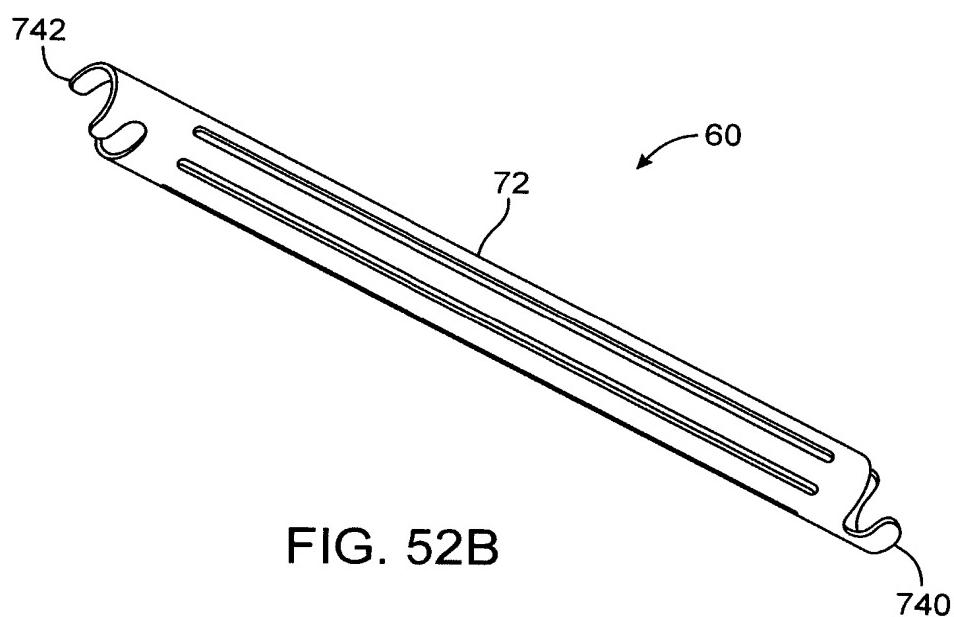


FIG. 52B

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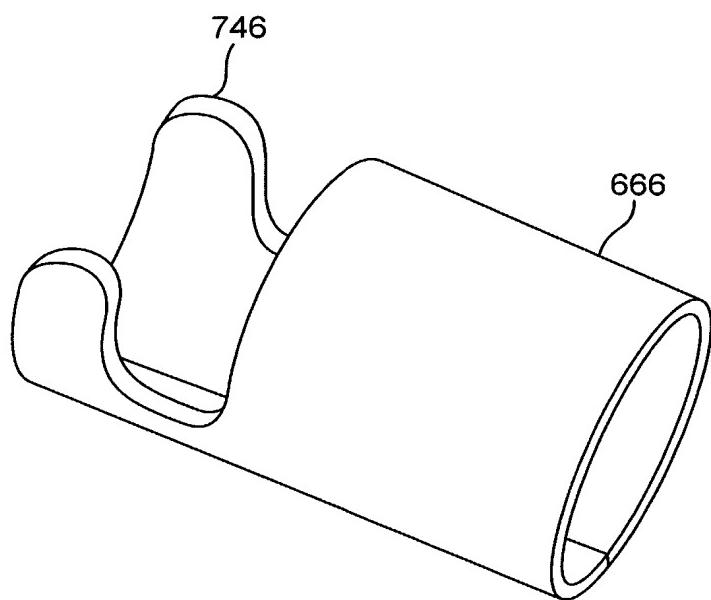


FIG. 52C

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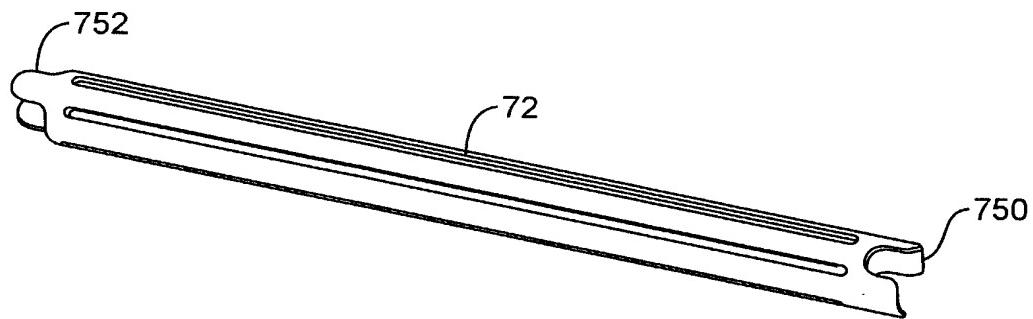


FIG. 53A

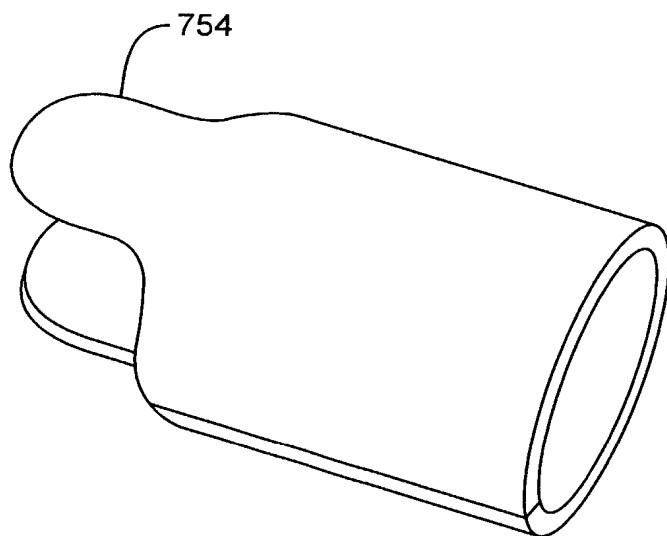


FIG. 53B

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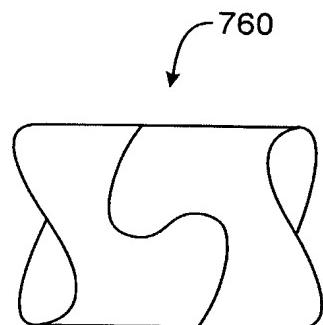


FIG. 54A

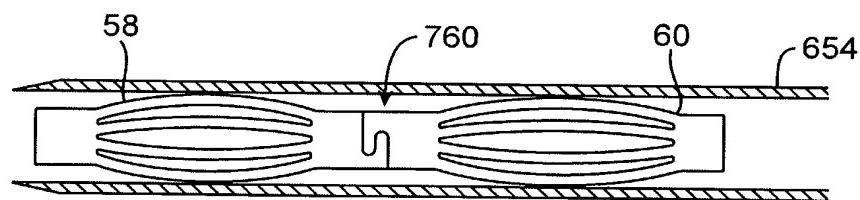


FIG. 54B

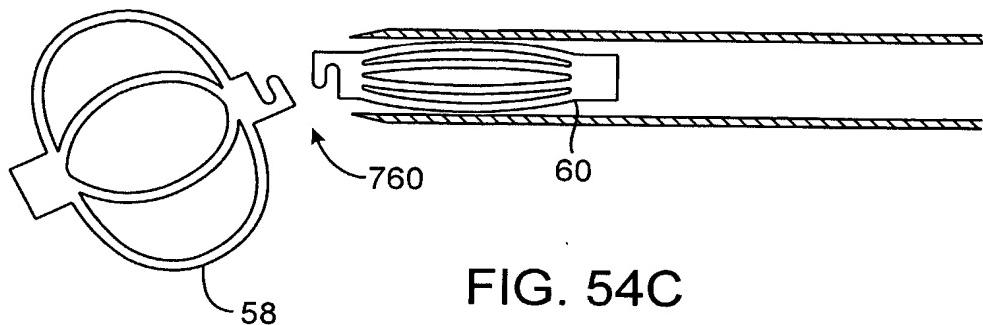


FIG. 54C

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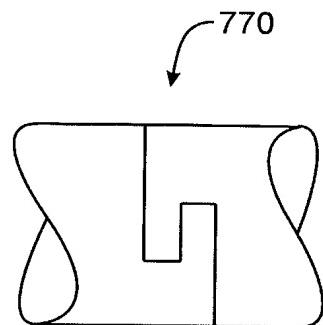


FIG. 55A

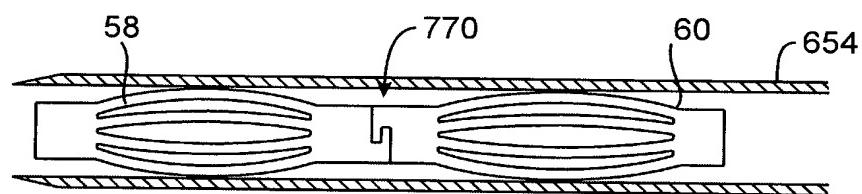


FIG. 55B

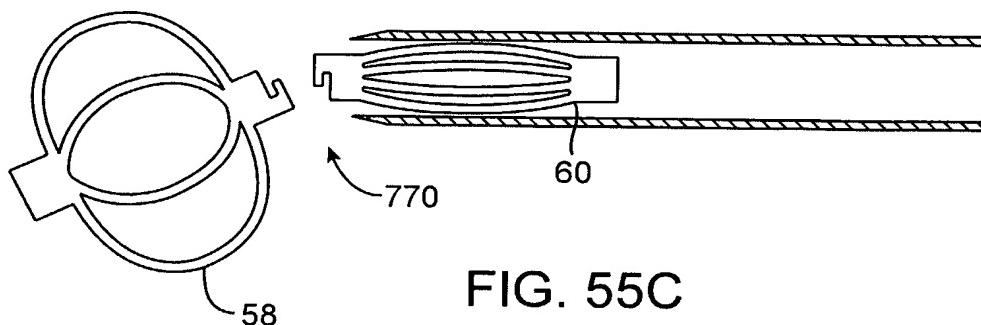


FIG. 55C

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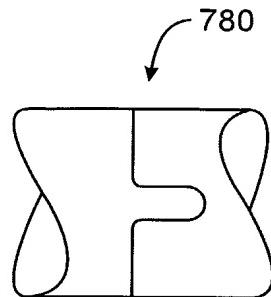


FIG. 56A

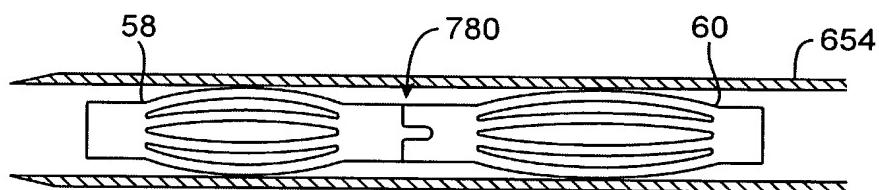


FIG. 56B

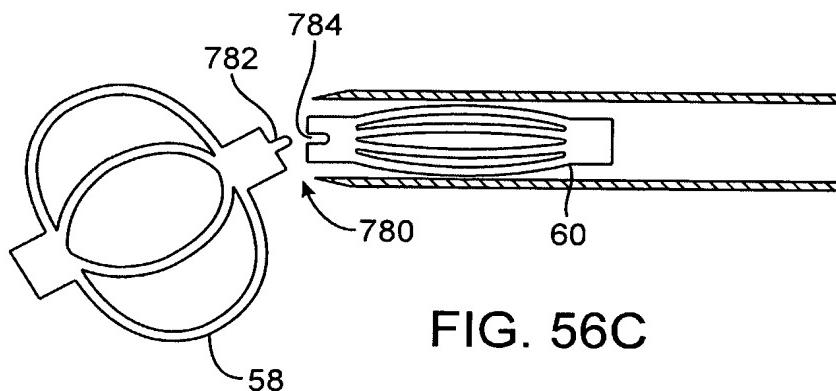
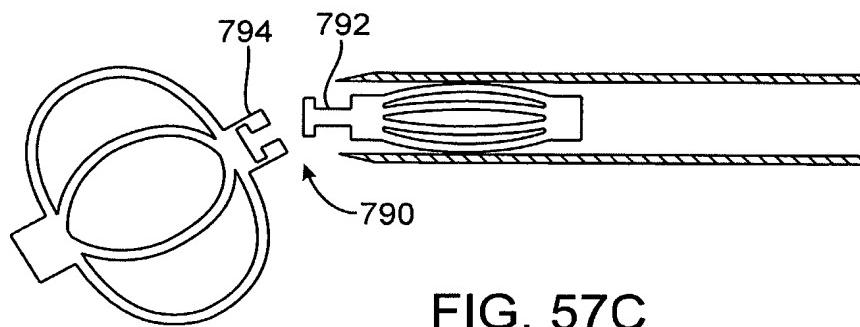
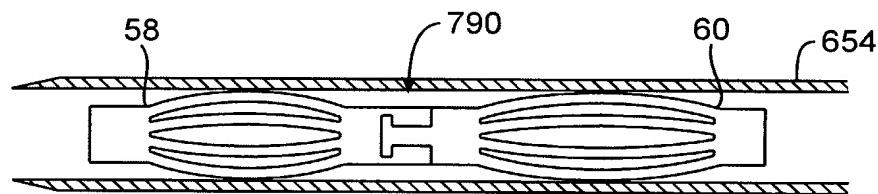
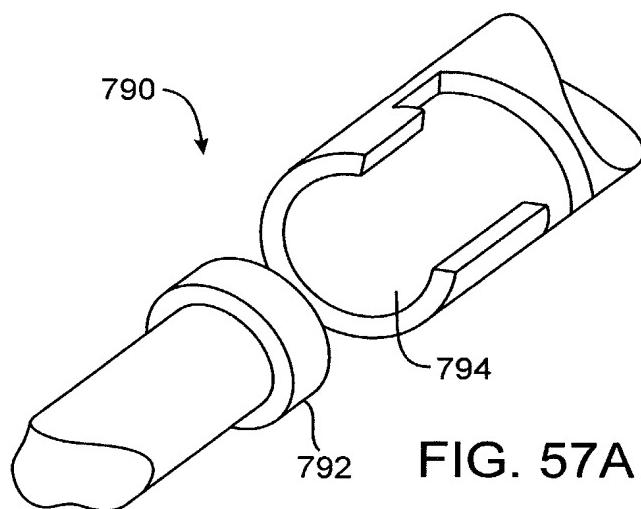


FIG. 56C

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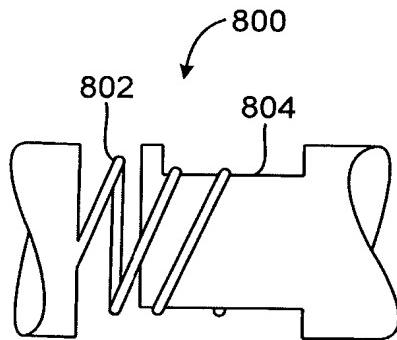


FIG. 58A

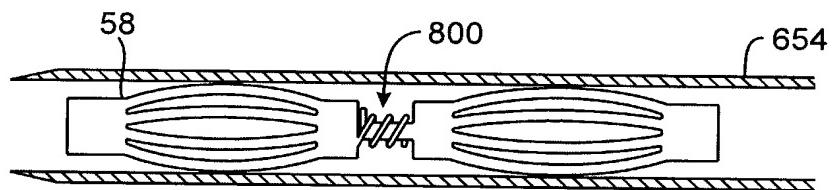


FIG. 58B

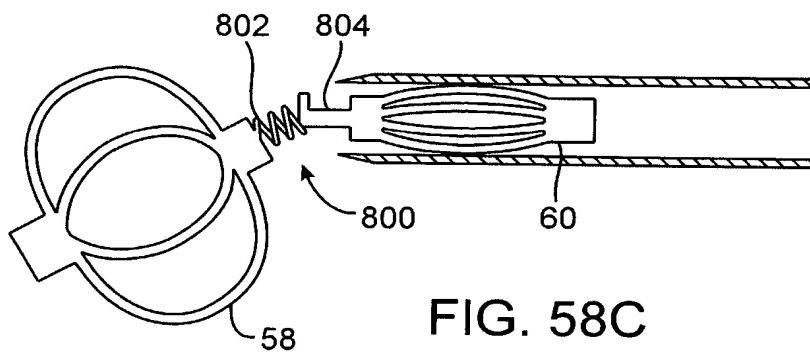


FIG. 58C

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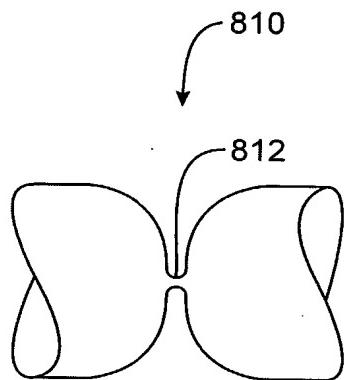


FIG. 59A

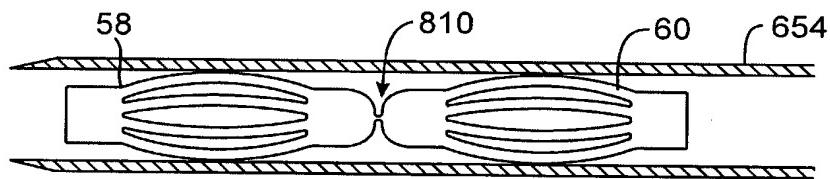


FIG. 59B

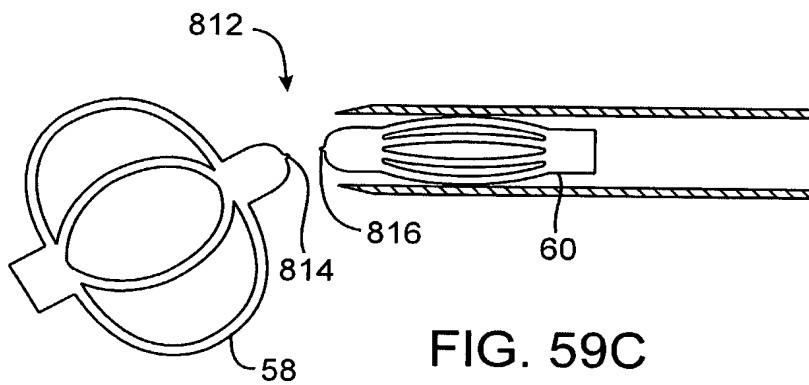


FIG. 59C

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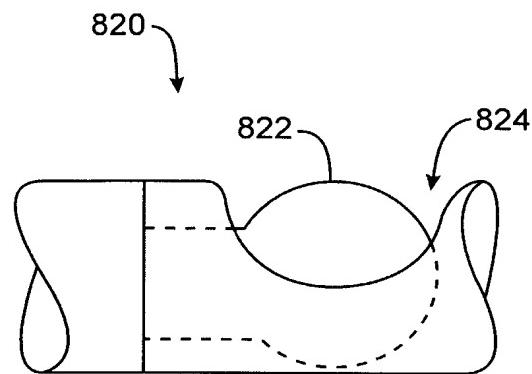


FIG. 60A

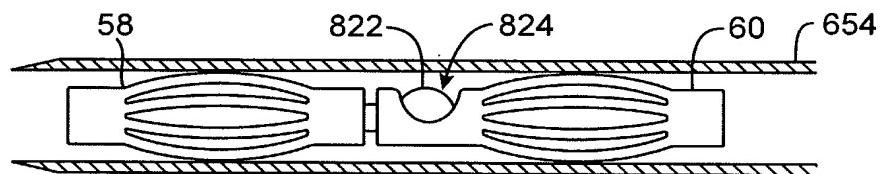


FIG. 60B

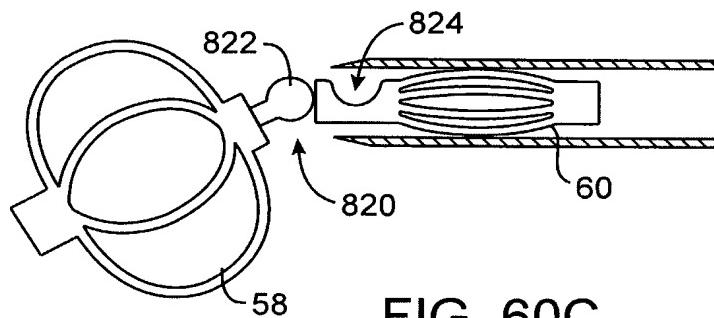


FIG. 60C

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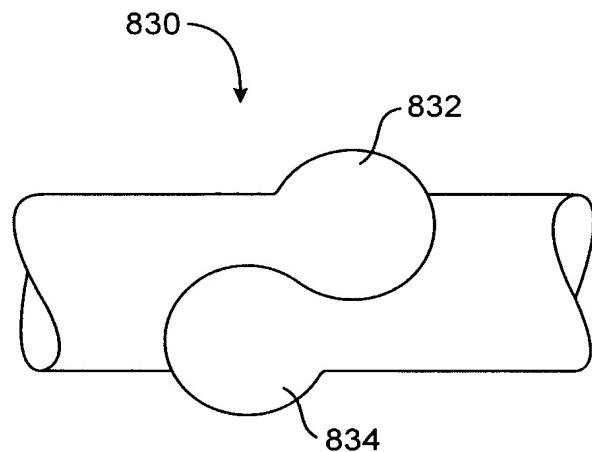


FIG. 61A

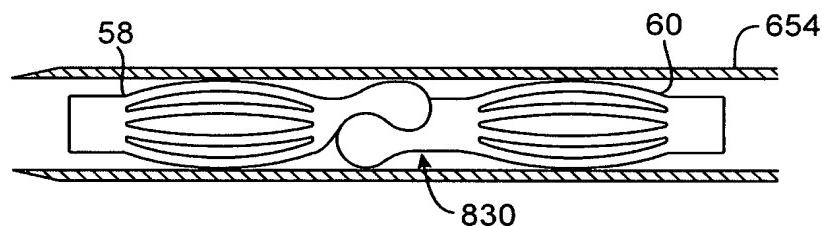


FIG. 61B

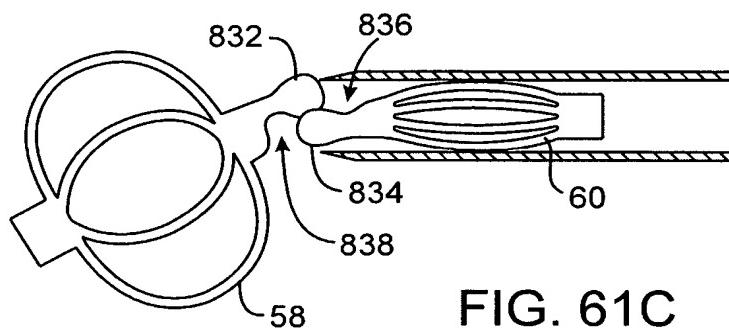


FIG. 61C

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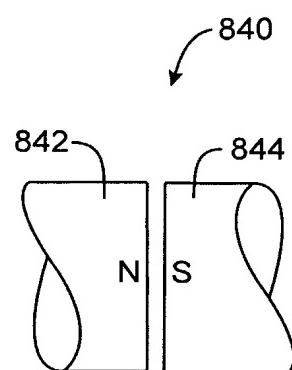


FIG. 62A

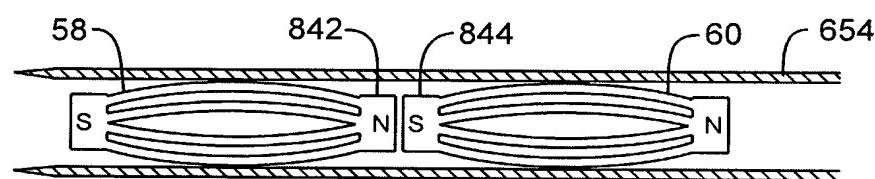


FIG. 62B

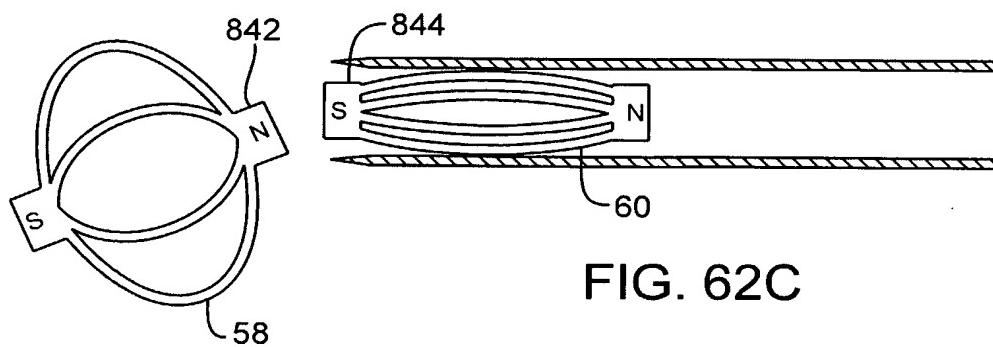


FIG. 62C

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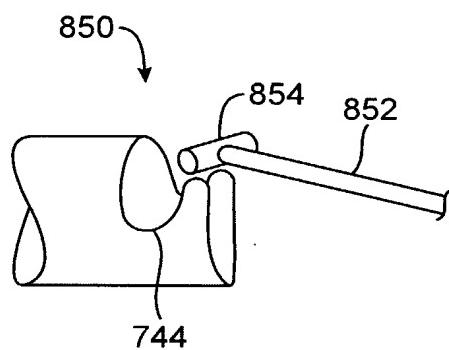


FIG. 63

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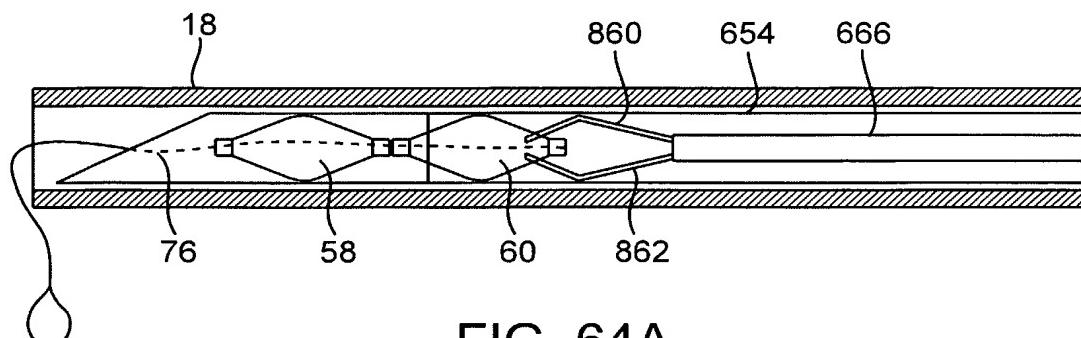


FIG. 64A

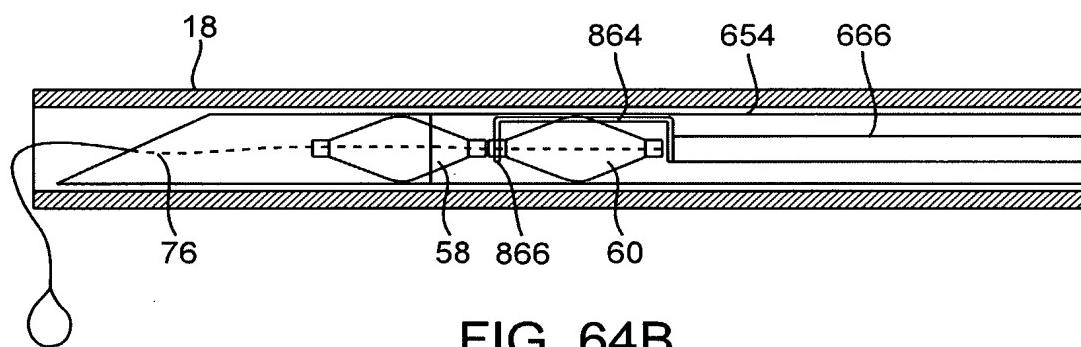


FIG. 64B

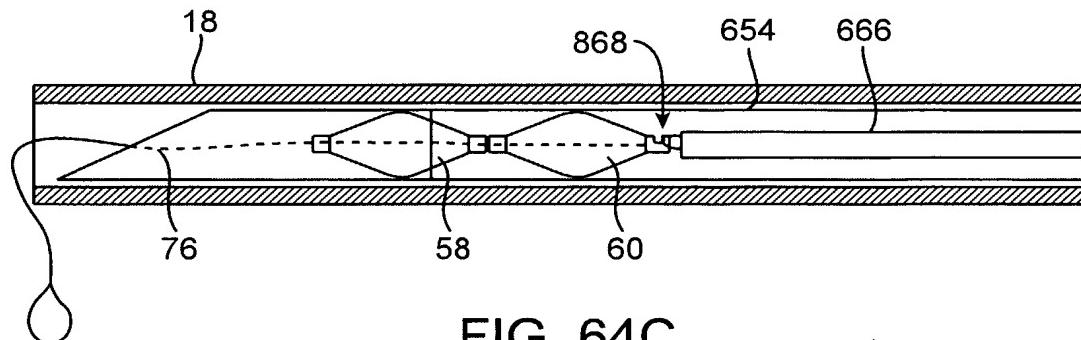


FIG. 64C

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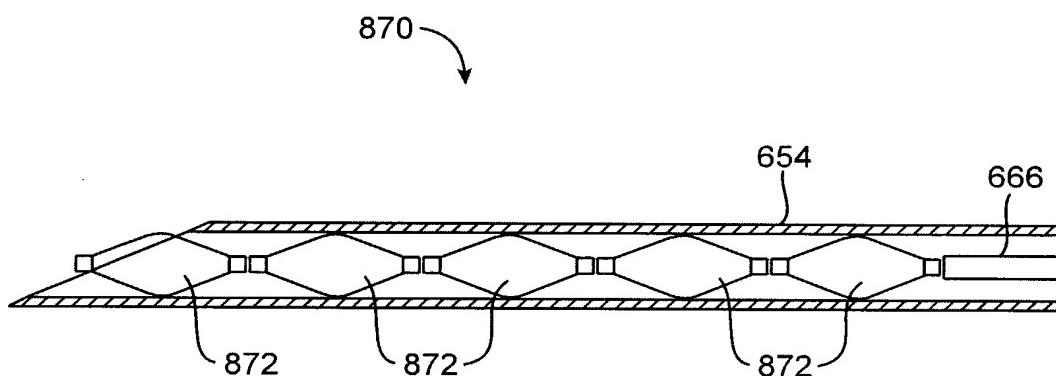


FIG. 65

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